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13. ABSTRACT (Maximum 200 words)

We devised a set of sensors for the vital signs of troops with each sensor providing radio transmission to a personal receiver unit. The project is part of an overall program with the sensor development at the University of Tennessee and other work done under separate contract at Oak Ridge National Laboratory. Device prototypes were constructed as application-specific integrated circuits (ASICs), each containing a radio transmitter of 1-2 meter range. These are termed "telesensors". A telesensor chip for body temperature was fabricated and demonstrated to transmit temperature with an accuracy of 0.1 deg C using spread-spectrum radio transmission. Wireless pulse-rate signals were also demonstrated. The body-temperature telesensor is sufficiently small (3 mm X 3 mm) to fit within the ear canal. The chip developed needed external components which could only be eliminated with further work. Benchtop systems for blood-pressure and respiration were demonstrated with wireless radio transmission. The receiver unit is composed of discrete components and interfaced to a laptop computer. A receiver with long-range transmission was unfinished.

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Miniaturized Biosensor/Transmitter Systems:

MEDICAL TELESENSORS

FINAL REPORT---JUNE, 1999

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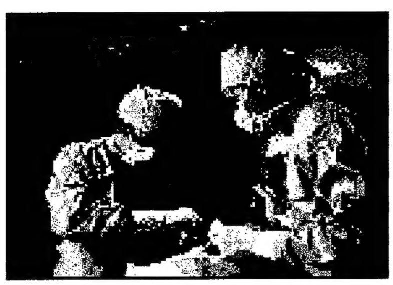
FROM THE ASIC PRODUCTION CLEAN ROOM TO THE SURGERY:



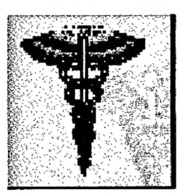


TABLE OF CONTENTS

CHAPTER 1
BACKGROUND

1.1. INTRODUCTION

This study is concerned with the use of self-powered, combined sensors and transmitters which measure and report the vital signs of troops in the modern combat zone. The combination of a sensor for one or more vital signs with either a radio-frequency (RF), a magnetic-field transmitter, or an infrared transmitter is herein termed a "medical telesensor". The requirements for practicable medical transmitters are that they:

a. be unencumbering and noninvasive;
b. have negligible weight;
c. have a performing lifetime appropriate to field use;
d. have a shelf life suitable to the intermittent nature and unpredictability of armed conflicts;
e. produce no significant electronic signature marking troop locations on a battlefield;
f. provide reliable data in a variety of hostile environments and in locations with dense vegetation or underwater;
g. give only readings of the vital signs of the *wearer*;
h. produce no transmissions affecting electronic devices, communications, or other military equipment regardless of proximity;
i. provide no signals of false alarm;
j. be amenable to mass production and other cost-reducing methods of manufacture;
k. be amenable to rapid and simple application to individuals;
l. be cost effective, disposable, and easily replaced;
m. be physiologically nonirritating to troops in prolonged situations;
n. have a dual-use nature to allow for civilian applications;
o. do not naturally pass from the body;
p. be self-contained and require no contact of specific points with the ground;

q. function regardless of body position or motion;

r. permit redundancy of measurement of vital signs so as to report adequate data if one or more telesensors fail.

s. permit economical, systematic coding for identification purposes;

t. survive the rigors of transportation without specialized and expensive packaging;

u. can be produced in ample quantities by a variety of manufacturers;

v. are removable with nontoxic agents;

w. require minimal training for the wearer and for medics;

x. can be adequately powered by thin-film batteries or by metabolic activity;

y. provide sufficient data for diagnostics and triage; and

z. require no receiving equipment of a prohibitively expensive, massive, or nontransportable nature, but have the capability of responding only under coded query.

These requirements are quite obviously not the only requirements which must be met by medical telesensors, but the list indicates the extraordinary extent of the necessary properties. In future testing and deployment there will be additions to this "abc" list, not the least of which will arise from the well-known axiom that even the simplest things become difficult in a combat zone. The abc list also demonstrates why medical telesensors have not been previously employed, since it is evident that only the latest technological advances are capable of addressing the performance, ergonomic, and economic factors described above. For example, it has only been recently that inexpensive, monolithic, custom, integrated circuits (application specific integrated circuits, or ASICs) have become within economical reach of small groups of engineers and scientists who are developing new and specialized devices. Moreover, such developments as have occurred in the digital cellular telephone market and the pager market are of substantial impact on the availability of designs for integrated circuits, encryption and encoding methodologies, and numerous other advances due to economy of scale in the civilian marketplace. Additionally, it is well-known that satellite communications and global satellite positioning equipment are now readily available to the military telemedicine program. Finally, the advent of modern computer workstations and software with the capabilities of circuit design and performance simulation has allowed small-team engineering of custom circuits involving hundreds of thousands of transistors. These advances have been complemented by the development of new types of sensors, of new data analysis and compression software, and of software involving neural network concepts that allow massive amounts of information to be efficiently turned into useful knowledge.

The aforementioned technological and scientific advances show only why the use of medical telesensors is not already extant; they do not show that the development and application of medical telesensors in the modern combat zone is in fact at hand. It is the purpose of this report to describe the progress made in developing medical telesensors.

The issue of use must be well-defined before results can be reasonably considered. In this report a "casualty" is defined to be an individual who is unable to carry out his appropriately assigned duties due to abrupt and physically deleterious external influences.

An important delineation of the project concerns is the role to be played by the telesensors. If the only requirement is that an individual be determined to be alive, then the role of medical telesensors is much simplified. In fact, reliable data of this nature would be of considerable value. However, it was premature to limit medical telesensors to this task at the outset as much of the same technology can be effectively used for determining casualties. At the other extreme of reasonable expectations is a system which would permit diagnosis of all possible physical injuries. The diagnosis of an unconscious individual who may be hemorrhaging internally or delineation of the state of an individual with a brain injury or spinal cord injury is, for example, a very difficult, but important potential task. In one instance the individual should be revived if possible, while in the other instance it is prudent not to induce consciousness. Similarly, a complete diagnostic capability would include the need for diagnosing individuals subjected to chemical or bacteriological warfare agents. Again this is an important task, but only one of a large variety which would pose a diagnostic problem even in a modern hospital. Therefore, this study began only at the simplest and most valuable technology and proceeded systematically. The important question of diagnostic role cannot be completely addressed here and must in fact await further developments with regard to actual medical application in a variety of test situations. A thorough discussion of the new diagnostics, which may be possible as a result of long-term monitoring of large numbers of individuals using medical telesensors, can only be mentioned at this stage with regard to the possible outcomes of the technology. However, the potential usefulness of the data by either medical corpsmen or physicians is naturally included in order to partially specify where future research and development may prove to be of considerable value and where testing may provide new paths. Clearly, it is not at present feasible to use medical telesensors to determine every possible casualty, but the possibility of determination of a variety of casualties within the first minutes of occurrence must be examined. The traditional marker for this is the "golden hour"---the hour immediately following injury in which 70% of deaths occur.

Another consideration of the potential use of medical telesensors that bears upon the properties considered in this study is pre-symptom diagnostics. For example, capnography

(the measurement of carbon dioxide in exhaled breath) can be used to diagnose bacterial infections up to three days before any physical symptoms are displayed. This would be useful information in the days immediately preceding combat so as to permit use solely of able-bodied troops. However, the project was not taken to this stage as such work was beyond the scope permitted.

1.2. OTHER RELEVANT PROJECTS OF THE MILITARY

This study would be derelict in content without mention of the fact that the Defense Advanced Research Projects Agency (DARPA) Electronics Technology Office (ETO) has funded several projects which bear upon the feasibility of medical telesensors. A good example is the University of Virginia's Center for Semi-Custom Integrated Circuits, which utilized DARPA funds first via a RASSP award in 1993. This Center is currently working on monolithic telesensors for sensing corrosion in buildings and bridges. They were funded by the author to assist in the making of an ASIC (Application Specific Integrated Circuit) which would function as a monolithic, self-powered, self-contained, body-temperature telesensor. Their preliminary work is quite useful to the final results and is discussed in later chapters. Other relevant university-operated centers include the Advanced Microelectronics Center at the University of Mississippi and its allied corporation, the foundry at Auburn University, and the DARPA-originated MOSIS chip foundry at the University of Southern California. The MOSIS foundry offers the opportunity for design checking and obtaining small quantities of ASICs at reasonable cost for the testing phase of development. Internet addresses for these ETO-funded centers are given below. The University of Tennessee also offers a site for updates on microelectronics and the site is included in the list.

Another benefit of DARPA ETO funding is the advantage offered by SEMATECH, which provides continued advances in chip technology. In particular, the combination of sensors, microcontrollers, and transmitters will require some of the methodologies pioneered by SEMATECH. SEMATECH's internet page is included in the microelectronics site list. The industrial partners in SEMATECH include many of the sources of modern integrated circuits.

This discussion of ETO-funded relevant projects is far from complete, and the reader is referred to the ETO internet site for further information. A low-resolution image (72 dpi) of some of the ASIC artwork done at the Mississippi site is shown below.

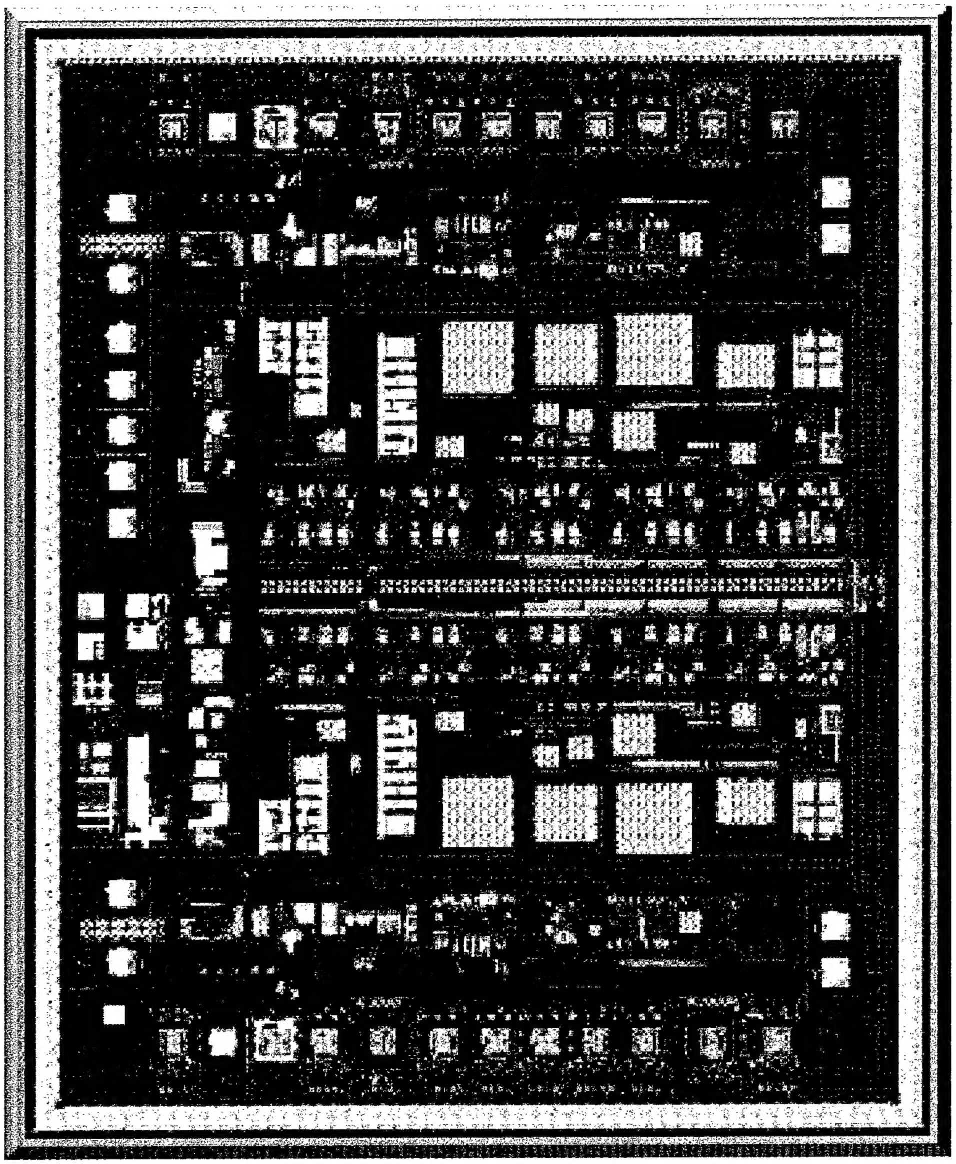


Figure 1.1. Artwork at 72 dpi shown for an ASIC designed by the Advanced Microelectronics Center in Jackson, Mississippi.
This is a SYSTEM ANALOG ASIC (SAA). The SAAis the heart of an alternative fuel system. The ASIC provides signal processing of 2 magnetic reluctance TDC signals as well as Hall effect signals. The ASIC provides programmable attenuation, filtering, peak detection, ADC, and DAC's to provide analog and digital representations of the TDC signal. Auxiliary circuitry on the ASIC provides filtering for the O2 signal, knock signal generation monitoring of power supply voltages, and fuel gauge information. The ASIC is highly configurable via a serial interface bus that can independently program the two TDC channels as well as relay fuel gauge information and configure the O2 and knock circuitry.

RELEVANT INTERNET SITES FOR ASIC INFORMATION:

http://www.mentorg.com/asic/asic_index.html	MENTOR GRAPHICS
http://www.isi.edu:80/mosis/	MOSIS (USC)
http://www.aue.com/cobra/CapFast/capfast.html	PHASE 3 LOGIC, INC
http://www.cadence.com/s&p.html	CADENCE DESIGN SYSTEMS
http://csis.ee.virginia.edu/info.html	Univ of VA CSIC
http://eto.sysplan.com/ETO/	DARPA ETO
http://microsys6.engr.utk.edu:80/ece/msn/	Univ of TN EE
http://www.aue.com:80/aue_home.html	Univ of MISS-Jackson
http://www.sematech.org/public/home.html	SEMATECH
http://www.synopsys.com	SYNOPSYS
http://arioch.gsfc.nasa.gov/wwwvl/ee.html	LIST OF MANY SITES
http://www.ornl.gov/~11r/TELESENSOR_ASICs.html	AUTHOR

A NOTE ON THE HISTORY OF SOFTWARE FOR ASIC SIMULATION:

The modern ASIC is made possible by the availability of design and simulation software for complex circuits. The first such program of real consequence was SPICE, which was developed in 1971 and which was based on earlier work using the FORTRAN programming language. In general, a linear circuit can be represented mathematically as a matrix, which can be handled with the standard tools of linear algebra, and FORTRAN was and remains a useful language for mathematical algorithms, having a legacy of libraries for a variety of calculations. SPICE offered many solved circuits that could be incorporated into more complex circuits, and it offered several real-device models. A considerable demand for SPICE was due to the very high cost of mistakes in the design of high-volume integrated circuits, a phenomenon of the extraordinary progress since the development of the first integrated circuit by Jack Kilbey of Texas Instruments, Inc. in the early 1960's.

SPICE could be run on the minicomputers arriving on the scene in large quantities in the early 1970's from companies such as Hewlett-Packard, Inc. and

Digital Equipment, Inc., and it was an invaluable tool for the electronics industry. By 1975, SPICE2 was being circulated with greatly improved and expanded device parameters, better and faster analysis of transient response (mainly through the use of new timesweep-control algorithms), and improved numerical routines for integrating various signals. It also had better superposition routines, and gave impetus to development of many transistor-transistor-logic (TTL) circuits. (A relatively high-power-demand technology) SPICE2 was last updated in its FORTRAN-compiled-language form in the early 1980s. As minicomputers gave way to UNIX workstations in the mid 1980's, there was a demand for SPICE-based circuit design and simulation in the C programming language, but with improved CAD features. SPICE3 was slowly developed into this environment and was married with a graphical post processor, added digital analysis capabilities, and could perform dispersion-equation analysis, and could deal with transmission-line analysis with complex impedences. Programs such as the freeware "Magic" provided at the University of California at Berkeley permitted easy circuit layout. The commercial electronics CAD industry offered several versions similar to SPICE3. In the late 1980's, Cadence Design Systems, Inc. offered electronic CAD based on SPECTRE, or rather a modified form of this SPICE-like program. A host of companies, including particularly Synopsys, Inc. currently provide highly sophisticated microelectronic design and simulation software suitable for use with networked arrays of modern workstations. Today, many such programs in reduced form can be run on personal computers---particularly in networked environments, a popular form being PSPICE for Windows and Macintosh. Programs have progressed to the point of being able to simulate the actual doped silicon starting with low-level, few-transistor, design files and progressing to more sophisticated files on a network of desktop computers.

Synopsys is a leading maker of software for electronics CAD and in early 1996 donated $6.3 million in software to the Electrical Engineering Department of the University of Tennessee in Knoxville. Such a package permits very rapid design and simulation using networked workstations. Their web site listed above has dozens of pages of bulleted descriptions of their software. It is thus quite difficult to summarize such extensive capabilities as are needed for current ASIC projects---the variety of needs is simply too large. The field has now moved far from its state of only eight years ago.

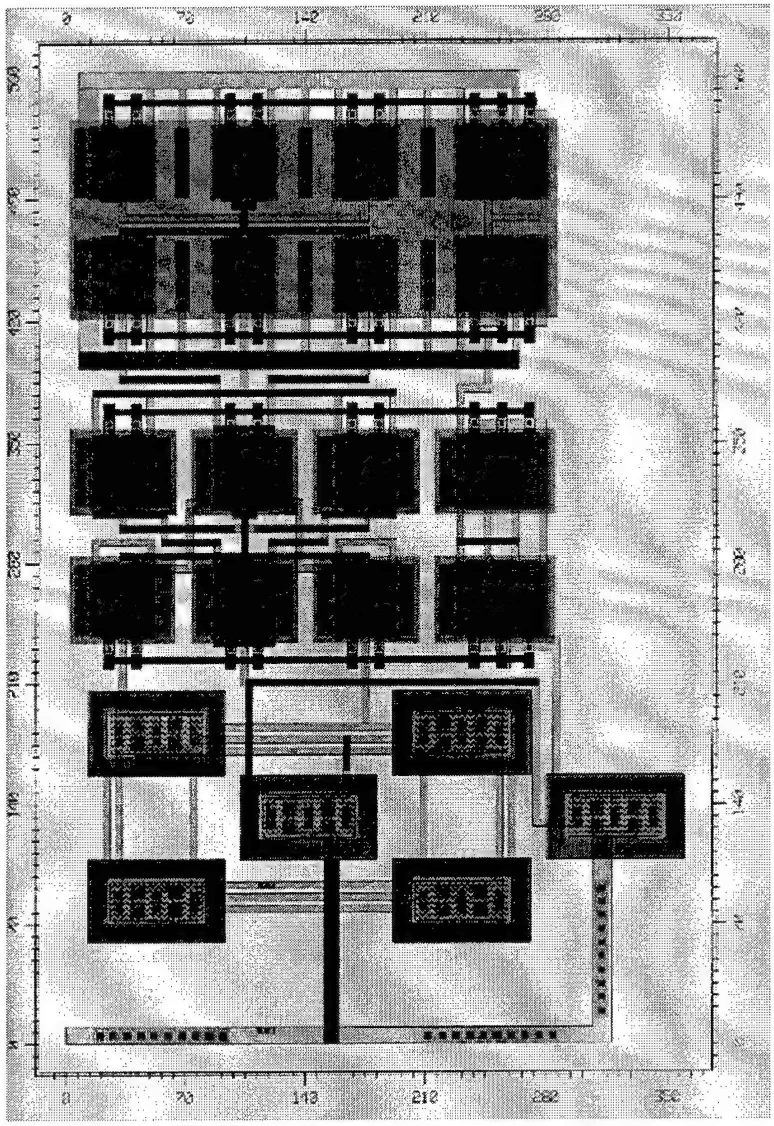


Figure 1.2. ASIC artwork for an Application Specific Integrated Circuit done at the Semicustom Integrated Circuit Center at the University of Virginia. The MOSIS chip foundry was selected for production of this ASIC, and the artwork was produced at the final stage of design and simulation. The circuit was designed using modern software on a network of workstations. This chip was fabricated under subcontract by the author and is discussed in later chapters

1.3. ORIGINALLY PROPOSED SYSTEM OVERVIEW

The following is a very brief overview of the systems proposed originally to the Defense Sciences Office (DSO) of DARPA under the present contract with MRMC as selected by DARPA's Dr. Richard Satava. This system represents part of a broad concept for use of medical telesensors, and was subject to change as it encountered other projects contracted elsewhere under the same program and as development proceeded. The description is strictly conceptual and is based upon original plans of the author in seeking to delineate the model used for the strategic goals of the research and development and in developing actual prototypes under MRMC contract. The description is given for referencing the actual final results with the original goals, some of which were not met for a variety of reasons. In practice, the main problems arose from difficulties with suppliers, a bad set of wafers produced by the Hewlett-Packard fabrication foundry (costing the project several months of engineering time despite the fact that the wafer was eventually fabricated at the original hardware cost), loss of personnel due to late arrival of funds when the President delayed signing the Defense Appropriations Bill, and difficulties associated with attaining sufficient models of the analog circuits on silicon. Nevertheless, excellent results were attained in that the point was reached at which commercialization proposals from private industry have been accepted for production of one of the medical telesensor ASICs.

A system of Body-Worn Medical Telesensors (BOWMETs) was planned which would radio-frequency (RF) transmission over approximately a 1.5 meter range with frequencies which would lie in a band selected from between 340 Mhz and 2.45 GHz. (Final choice was the 902-928 MHz band). Each medical telesensor was designed to transmit to a helmet-worn or belt-worn, intelligent, transceiver unit. This Master Individual Transceiver Intelligent Monitor (MITIM), or Executive Unit in simpler form, was planned to be capable of alerting medical personnel if it is deemed necessary to do so from its received data and programming. Each BOWMET measures one or more vital signs. The majority of BOWMETs as planned consist of a single ASIC, set of ASICs, or multi-chip module that is powered by a thin-film, lithium-ion battery deposited on a substrate that also bears a radio crystal and antenna. Each BOWMET can be coated with a thin plastic or silicone coating and has no external leads, but can be applied intra-aurally or attached by area-specific adhesive and/or mechanical mount e.g. universal-fit ring on finger, plastic insert on tooth, bandaid, etc. The size of a typical BOWMET is in the three-millimeter to fraction-of-millimeter range in all dimensions excepting certain cases described below. A BOWMET can operate on a duty cycle in measuring vital signs, and transmits to the MITIM only at pre-set intervals or when queried or when a significant change is detected.

The duty cycle in measuring vital signs is primarily set for reasons of increasing times between recharge cycle for a given energy demand, the batteries being allowed to trickle-charge capacitors that discharge to fire the transmitter.

The use of coded RF technology allows each RF BOWMET to transmit when instructed to do so by the MITIM and spread-spectrum transmission is used. This technology is a simpler alternative to networked systems such as the body Local Area Network(LAN), but gives the same result. That is, the transmissions would not cause problems to the units worn by other soldiers and they would not interfere with electronic weapons systems as the spread spectrum energy in any given frequency bandwidth is below the noise threshold. Alternatively, a narrow-band transmission at very short range would be insufficient to produce interference. Each BOWMET has on-board a sensing transducer, a preamplifier, an analog-to-digital converter, digital-signal processing, logic circuits for the spreading, mixer circuits, a phase-locked loop for referencing the frequencies to the crystal, and a transmitter. In lieu of analog signal-processing electronics such as logarithmic amplifiers, signal dividers, etc. that are needed for vital-signs measurements, part of the logic can be programmed to carry out certain of these tasks. It further is used to control the characteristics of the transmission. *The combination of the disparate elements in a monolithic configuration became feasible only in late 1996 due to our successes with analog designs and further advances may be due in part to the availability of a formerly classified-work foundry.*

Each MITIM consists of a microprocessor and the usual supporting memories, interfaces, clocks, etc. together with up to three different 1.5 to 2-meter-range transmitters, a 1.6-mile-range RF transmitter, and a 0.5-mile-range infrared transmitter, as well as a querying transmitter. Only one transmitter is active at a time. No long-range transmission would occur unless trauma of a pre-set degree is detected. In this case, the MITIM would send an alerting, coded, pulse to medical personnel via spread-spectrum transmission. The pulse would indicate three levels of trauma or signal a fatality, and would be coded with an identifier and a location code. If and only if queried by medical personnel, the MITIM would then respond with a compressed-data pulse encoding the vital-sign data and could be instructed to communicate with the individual and report the results, e.g., "Touch your wristwatch to your nose."---a part of a standard medical test that would determine data on the conscious state of the individual. Such transmission would utilize spread-spectrum technology and could be sent under the noise level.

(The MITIM units were not finished at the conclusion of this project due in part to the development of long-range transmitters for the Personal Status Monitor by other

contractors and the consequent desire to not duplicate the effort needlessly. Unfortunately, the designs and protocols for the long-range transmitter were not made available to us as the contractor (Sarcos, Inc.) retained the needed proprietary information and is no longer funded for this project.)

The medical telesensors can be further developed as ASICs to produce the following data above and beyond body temperature:

1. heart rate;
2. level of arterial-blood dissolved oxygen;
3. blood pressure;
4. blood volume;
5. Na-ion concentration on the skin; and
6. respiration rate.

A number of additional medical telesensors have been studied, but are further removed from the development stage. These include a device that is capable of detecting subaudible body "sounds" that are diagnostics for a variety of injuries (including internal hemorrhage), and a basic EEG unit. The latter is currently in useable wireless form, but the radio signal has not been spread and ASICs have not been fabricated. Certain biochemical sensors (sensors which use a film of highly selective molecules to garner compounds for concentration measurements) which would sample perspiration, leakage urine, or saliva, for antigens or toxic compounds are also being researched and results have been published. However, the coupling of these to the transmitter is not yet complete. Finally, silicon microaccelerometers (microcantilevers) and position sensors are good candidates for future medical telesensors, but are still in the early stages of research.

The list of data shown above would be measured by several different types of sensors with considerable redundancy. Only redundancy in the blood-pressure data would require any significant package size and this is *only* true because of the need for redundancy. Already available is a device which measures blood pressure from data on the difference in arrival times of the pulse at different points on the body. A similar device is currently incorporated in a wristwatch from Casio, Inc., but requires the user to perform a voluntary action and is better packaged as a medical telesensor pair needing no voluntary action for the present purposes.

In addition to medical telesensors, the military has also funded research and development in injury telesensors such as the past form of the Personal Status Monitor

(unsuccessful to date) and the still-ongoing Sensate Liner. The latter device measures projectile impact data and would possibly form part of the overall system transmitting to the MITIM. These and other sensors are beyond the scope of the present study, but are annually considered at the related military conferences. Integration of disparate projects is greatly facilitated by such conferences and contractor meetings, and a series of "one-on-one" meetings has also proven fruitful.

A final clarification of this study is the term "telemedicine". Currently this term is primarily used to describe the transmission of medical images. As a result, it is not used below, but may be a source of confusion until such time as medical telesensors are widely used.

An overall view of the related military projects is very useful and is partly available, for example, on the DARPA DSO internet home page. The great variety of projects requires flexibility to allow for many new and important developments, and this means that the present study is of transient value. A later study should be conducted with an improved scope and more comprehensive interconnections between all projects bearing upon medical telesensors. The MRMC homepage is very valuable in providing information on the military telemedicine program and on developments in field hospitals.

CHAPTER 2

CUSTOM INTEGRATED CIRCUITS

2.1. INTRODUCTION

Modern integrated circuits can be produced either on doped silicon or gallium arsenide, with silicon being much the predominantly used material. The production process for circuits is very similar for the two materials, although different chemistries are involved. In this section a brief description of the production process is given for silicon, and the further discussions of medical telesensors draws upon this basic knowledge. The use of gallium arsenide is described wherever it is appropriate, but this is an expensive technology.

The first stage in producing integrated circuits begins with the growth of large ingots of single-crystal silicon. This process is now very well refined despite its remarkability. The ingots are sliced into wafers which typically display the (100) crystal face of silicon on the surface, although the surface reconstructs into forms such as the 7x7 reconstruction due to the fact that the surface atoms see, of course, no other atoms above the surface. They therefore arrange themselves in a minimum energy state that is different in arrangement from that formed by the interior atoms (which see other silicon atoms on all sides of themselves). The 7x7 form implies that the surface unit cell is that much larger than the unit cell of the crystalline symmetry in the bulk. As a result, the electronic properties are different at the surface from the bulk electronic properties. The electron scanning-tunneling microscope has given us in the past decade actual atomic-scale-resolution images of the surface of silicon, and has allowed us to understand other semiconductors as well. It is the fundamental advances in surface physics that has allowed much of the substantial progress in optimal use of silicon and other semiconductors.

Following polishing and other surface treatments, each wafer is oxidized under a very pure oxygen atmosphere in a high-temperature furnace so that a controlled thickness of the oxide coats the surface. (A layer of silicon nitride introduced is omitted from the discussion for purposes of simplicity, but acts as a protective barrier in later stages of processing). A layer of photoresist is then coated onto the surface, the photoresist being a polymer that changes its physiochemical properties in any region that is exposed to light of a given spectral range. For example, exposure to ultraviolet light may cause certain photoresist polymers to crosslink and thus become very resistant to removal from the surface by the ensuing steps. The goal is to selectively remove only certain regions of the

photoresist so as to produce bare areas of the underlying surface which can then be etched away to expose the silicon to doping or metallization. The addition of photobleaching compounds, which are able to prevent exposure below a given intensity threshold, has permitted much crisper exposures. The result is much better definition of structures.

A mask is constructed for the photoresist layer by first using modern computer software to determine the geometry and sizes of the transparent regions of the mask, and then photographically reducing the size of a film that is prepared from the graphical output of the computer. Alternatively, the mask may also be prepared from photoresist. The mask is positioned and aligned by a device called a "stepper", which is also responsible for proper focusing of the exposing light. A silicon wafer with an array of circuits on it is shown in Fig. 2.1, while a stepper is shown in Fig. 2.2. Several mask changes can be made by the stepper, and a variety of circuits can be made on a single silicon wafer.

One should note that the above process is repeated many times before a wafer is finished and that cleaning steps occur in between the processes. Testing at various stages is also essential. Contamination of the process is ruinous and extreme measures are taken to prevent contamination by dust or human byproducts. The wafer fabrication process takes several weeks depending upon the size and complexity of the circuits.

Following exposure through the mask, the photoresist is developed and removed in the regions in which it is susceptible, and the underlying oxide layer can then be etched down to the silicon surface. At this point the silicon is doped with impurities to convert it into either a p-type or n-type semiconductor. In a p-type semiconductor the charge carriers are holes rather than electrons, a hole being a positive unit electronic charge that results from the absence of an electron from its usual site in the valence band. The above process is repeated many times in order to properly position the regions of p-type and n-type material, and ends with three or more depositions of aluminum contacts between the various semiconducting areas. A transistor is formed wherever a thin layer of one type of semiconductor is sandwiched between thicker regions of the other type, connections being made to both slices of "bread" and the "meat" in the middle. A diode results wherever an n-type region contacts a p-type region. This can be simply understood by considering that at a junction of a p-type and a n-type material the two different charge carriers diffuse across into the material on the other side of the junction where they become relatively immobile. This process continues at any given temperature until the electric potential thereby engendered prevents further diffusion. A junction potential is thus fixed. If an applied voltage opposes the junction potential (forward bias), then conduction can occur as the large diffusion current is partially released. But if the applied voltage is of the same

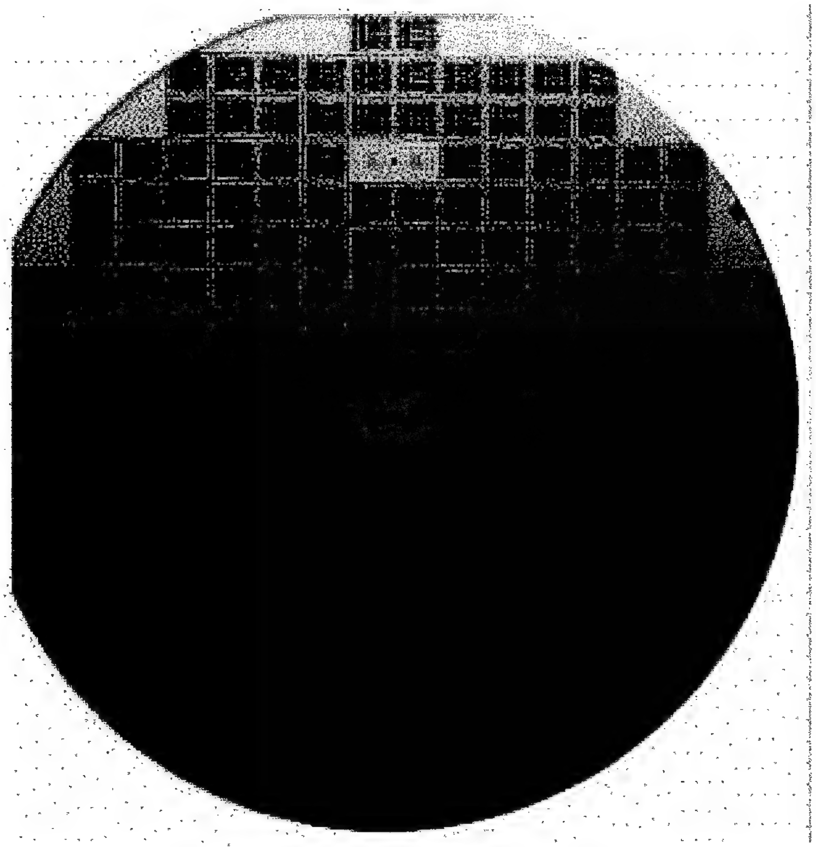


Figure 2.1. A six-inch diameter silicon wafer (one edge being slightly truncated). This wafer could have contained over ten thousand individual circuits and is only a few thousandths of an inch thick after processing. Inexpensive chips for consumer electronics are the smallest and most abundant on production wafers, but custom chips may be tagged on to such wafers due to the versatility of steppers.

Figure 2.2. A stepper system used for the mask and exposure of the wafer. The stepper sends ultraviolet light through the mask and a lens array that reduces the image. It must position, align, and focus the light to better than 0.1 micrometer as it steps from circuit to circuit in fractions of a second.

sign as the junction potential the holes and electrons may be attracted to one another, but are pinned by the applied voltage so that no conduction can occur (except for a small leakage current that is limited by the low conductance of holes in n-type materials and of electrons in a p-type material). Hence, rectification occurs. Capacitances and resistances can also be produced on the wafer. Circuits containing several million transistors can be made today. The actual size of two examples of this is evidenced in Fig. 2.3 and Fig. 2.4, which show modern microprocessors at actual size.

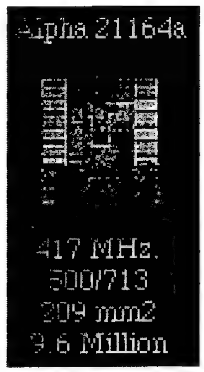


Figure 2.3. A microprocessor from Digital Equipment, Inc.

Figure 2.4. A microprocessor from Motorola, Inc.

The line-widths of the patterns of modern integrated circuits extend down to a small fraction of a micrometer. (Note that the microprocessor of Fig. 2.3 has 9.6 million transistors in the area shown.) The resulting higher packing density permits much greater speeds of operation. The limit to this is approached as the sizes of devices begin to cause nonclassical performance, focusing and exposure become impossible, or numerous other problems are encountered.

The above description of a simple transistor has been changed considerably with the advent of complementary metal-oxide semiconductor processes (CMOS). These processes greatly aid the production of ASICs in all areas of measure.

There are a variety of chip foundries in the United States that can provide low-priced custom integrated circuits on silicon or on gallium arsenide. A widely used foundry is the MOSIS facility at the University of Southern California. Whenever MOSIS or another initially chosen foundry cannot meet its schedule or cannot make a given type of IC, it is common to seek out other foundries. MOSIS sometimes uses the Hewlett-Packard foundry, for example, for certain CMOS integrated circuits. The resources for gallium arsenide are more limited, but currently are available in several US foundries.

Gallium arsenide is a type III-IV compound semiconductor used for making optoelectronic devices and high-frequency integrated circuits. GaAs has a charge-carrier mobility twice that of silicon and has a larger bandgap. The latter is exploited by Motorola in its GaAs Schottky barrier diodes, which have higher breakdown voltages (over 200 volts) and lower leakage currents than do silicon diodes. However, GaAs diodes also require higher forward voltages, so that the user must be satisfied with a tradeoff in characteristics. Motorola makes more than 50 GaAs integrated circuits. For transmitters working at gigahertz frequencies, an antenna on-board a chip should be designed to have the optimal impedance and should be amenable to production. In such cases GaAs is the preferred substrate. However, the recent "Bluetooth" initiative inaugurated by a consortium of industries involved in desktop computers and peripherals is taking the performance of silicon to the 2.45 GHz band for very short-range communication. This is an international band.

A laser diode can be constructed directly on GaAs, the emitted light originating from recombination of electron-hole pairs and being pumped by a dc voltage across a p-n junction. The diode wafer is its own resonant cavity, because the reflectance of the crystal-air interface is quite high at the lasing frequency (around 840 nm wavelength). The 840-nm wavelength is very important to oximetry as it is at 810 nm that the absorption of light by oxygen-saturated hemoglobin equals that of unsaturated hemoglobin. Thus, the 810-nm wavelength is a reference point for comparison of the absorption of light by the blood at

other wavelengths. The energy conversion efficiency of GaAs laser diodes is extraordinarily high, being about 50 percent.

2.2. SENSORS ON CUSTOM CHIPS REPORTED BY OTHERS

Several different sensors have been produced on silicon as fingernail-sized chips and are commercially available. Honeywell, for example, makes a pressure sensor and a magnetic-field sensor both of which are custom chips with on-board electronics. Analog Devices makes a temperature-sensor chip with an accuracy of 0.01 Celsius degree from -55 to 125 degrees Celsius. Shown below in Fig. 2.5 is a smart pressure sensor on a chip (Analog Devices, Inc.). This chip has its electronics placed around the pressure-sensing diaphragm in the center. In this geometry the space normally taken up by the mechanical support for the diaphragm hosts the various electronic circuits. These include a clock, an integrator, a comparator, and other circuits.

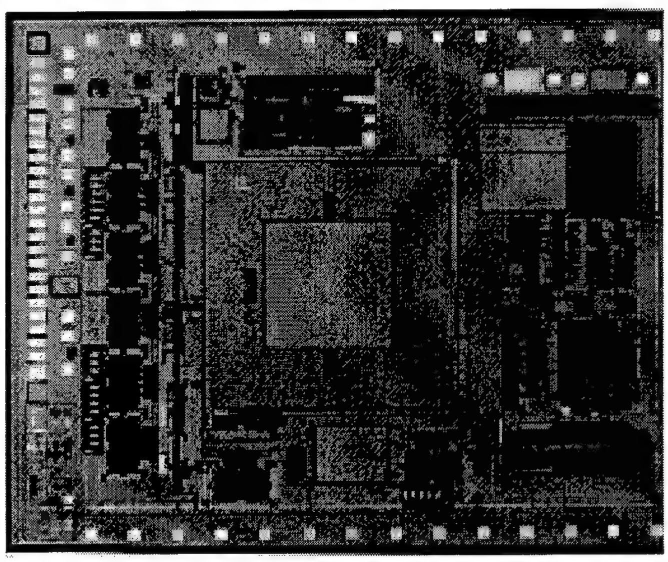


Figure 2.5. A Smart Sensor for Pressure with All Electronics.

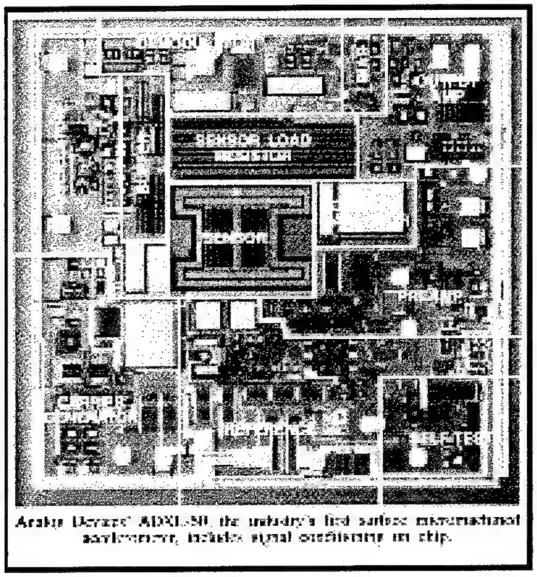


Figure 2.6. A Capacitive-Based Accelerometer from Analog Devices, Inc.

The applications of pressure and accelerometer sensors in chip form is widespread in the automobile industry due to such uses as occur for engine performance, anti-pollution devices, and air bags.

For photonic applications of sensors it is often necessary to have several wavelengths available simultaneously. The Jet Propulsion Laboratory in Pasadena has made the four-laser chip shown in Fig. 2.7. The intensity at each wavelength is shown in Fig. 2.8. The wavelengths can be altered in any of several ways, including the possible use of alternative semiconductor materials, and this would be valuable for pulse oximeter medical sensors. JPL also makes a laser anemometer on a chip. All chip-based sensors can be incorporated onto a transmitter chip or made as part of the new concept of multi-chip modules (MCMs). The MCMs idea allows several chips to function together in a much higher density combination than that which occurs with use of printed circuit boards.

Notice that in Fig. 2.7 there are wires that have been attached to the diode lasers. The use of the wires would obviously be eliminated in a completely integrated circuit as they would be replaced with deposited aluminum or gold leads. In almost all integrated circuits the deposited leads form all the interconnections and are brought to solder pads around the periphery of the chip. At this point, wires are attached which are considerably smaller than a human hair, and these go to points of the plastic or ceramic package that houses the chip. However, use has recently been made of the concept of "flip-chip" interconnections. In the flip-chip method, the chip is flipped over and the solder pads,

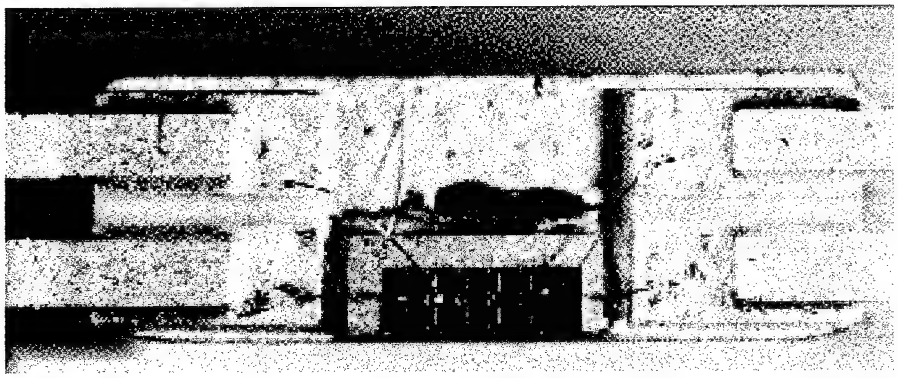


Figure 2.7. An Integrated Array (prototype) of Four Different Laser Diodes on a Single Chip.

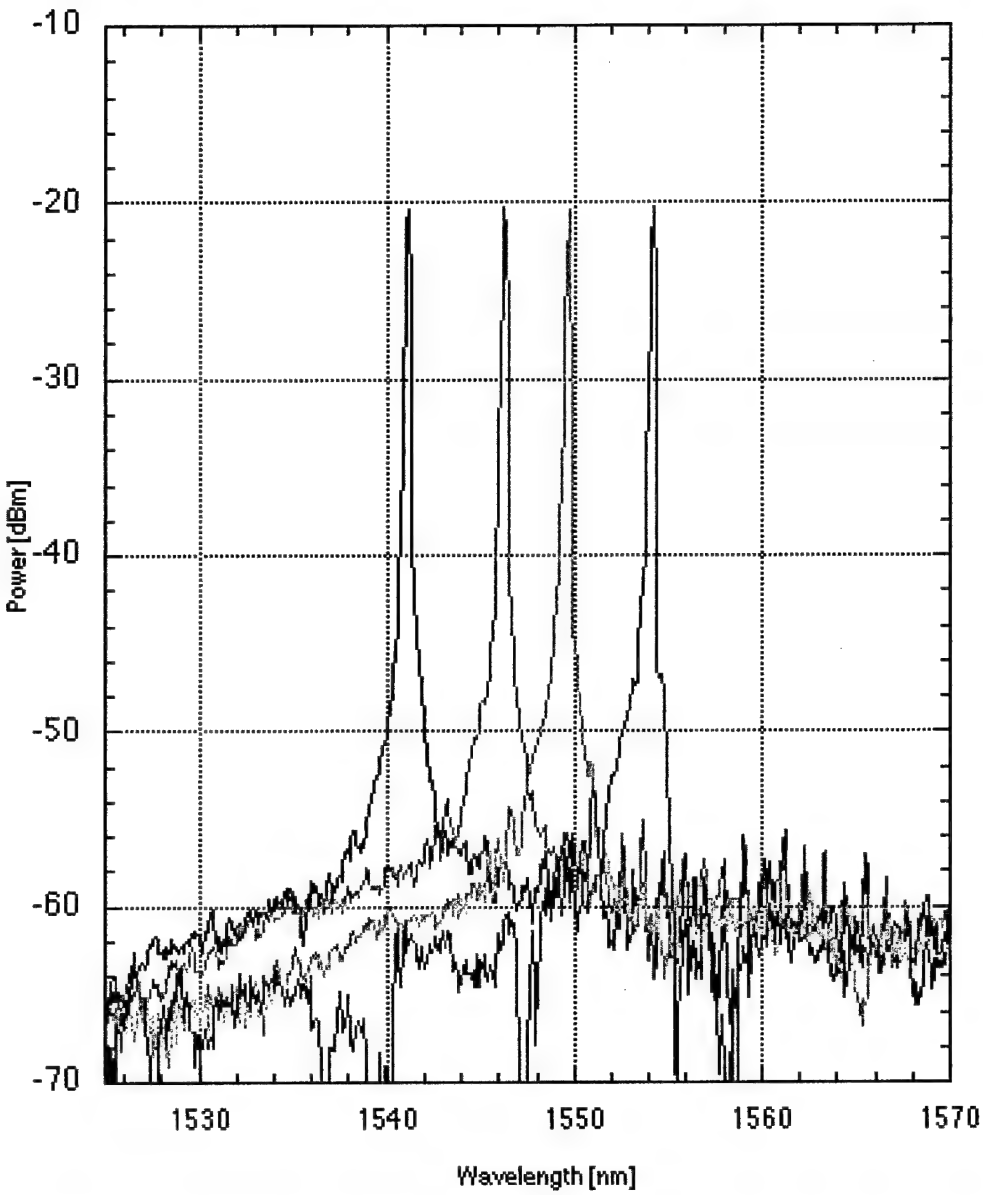


Figure 2.8. Output Power Versus Emission Wavelength for the Quad Laser Diode Array.

which are made on the undercarriage, are made to mate with the pads of another chip. Since the two chips are only about 0.008 inch thick, the combination remains very thin on the human scale, but does not require an increased area. If the chips are powered by on-board, thin-film, lithium-ion batteries, and if the external communication is by transmission in lieu of wires, the whole assembly is self-contained.

In terms of the detection of light with integrated circuit sensors, the situation is much more advanced. Texas Instruments now makes a chip that has a charge-coupled device (CCD) array and a conversion of the output to digital form in a monolithic package.

A variety of sensing chips are rapidly becoming available. AMC in Alberta, Canada has several microsensors, including piezoresistive, capacitive, and electrochemical, the functioning core of one of their sensors being shown below.

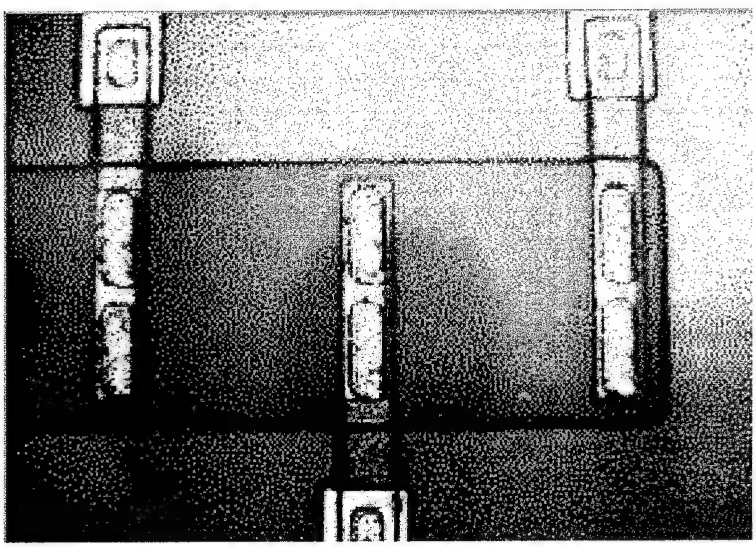


Figure 2.9. AMC Microsensor.

Nellcor, Inc., which makes a product line of pulse oximeters, exhaled-breath carbon dioxide sensors (capnographs), is in the early stages of putting a pulse oximeter on a chip. As of Nov., 1995, they put about 1200 man-hours of engineering time into the project. Unfortunately, some of this work will have to be duplicated, as Nellcor has expressed reservations about military-related projects, although they have thus far been quite cooperative with the author. A major task in carrying out the development of medical telesensors with efficiency and with guarantee of future suppliers is to politically buffer industries that are worried about such matters---especially with regard to such concerns as

proprietary information, meeting of detailed and changing military specifications, etc. It is difficult, but not impossible, to plan and make collaborations that effectively utilize the resources of industries without compromising their competitive position and without burdening their specifications infrastructure. These concerns must be handled on a case-by-case basis, and have thus far been gainfully addressed through the Offices of Technology Transfer at ORNL and at the University of Tennessee. The author has signed a proprietary information agreement with Nellcor that has permitted considerable progress for the project due to the advanced circuits developed by this leading manufacturer of pulse oximeters.

A superior concept for pulse oximetry has recently been developed at the University of Tennessee by the author. Using a modified pulse-oximeter front-end from Nellcor, we have been able to obtain the signal from within the ear canal from the carotid artery. This permits oximetry under conditions of low blood pressure as in a state of shock or other trauma. It also reduces motional artifacts and has no stray-light problems.

The unobtrusive nature of self-contained ASICs as medical telesensors can be visualized from Fig. 2.10 below. This shows two sensor chips on the author's finger. These are sufficiently small that they may be attached with surgical adhesive for extended periods without noticeable irritation. The chips are coated with a thin lucite film of low irritation quality. Thus, just as the attachment of a tick to one's skin can go unnoticed (until the tick swells considerably or moves), the same phenomenon allows any sufficiently small, noncaustic, attachment to be used.

Figure 2.10. Two sensor ASICs on the tip of the author's finger. When paired with a transmitter using an antenna and lithium-ion batteries on-board, these are self-contained telesensors.

CHAPTER 3

CURRENT MEDICAL TELESENSORS

3.1. INTRODUCTION

The use of vital-sign sensors together with transmitters has already become a commercial reality. For example, Polar, Inc. (http://www.polar.fi) has a heart-rate sensor for swimmers, the exceeding of a preset heart rate acting to trigger a magnetic-field transmitter which is received by a wristwatch receiver/alarm. The system operates to depths of 20 meters and uses a similar wristwatch-size sensor attached to the chest with a belt. The simplest transduction method for such applications is one that uses only skin conductance measurements to measure the heart rate. That is, as the pulse reaches a given region of the skin, the skin stretches slightly and this results in a longer conducting path between any two closely spaced electrodes. An advantage of the technique is that the dc conductance level is a measure of the sodium-ion concentration on the skin, this level being an excellent early indicator of trauma or stress (as in lie detectors). An optical sensor can see the skin move, but provides no measure of the Na-ion level (as could be measured with the swimmer's device, although it needs no data of this type). A photo of the receiver/pulse-display wristwatch is shown in Fig. 3.1 below.

Figure 3.1. The Receiver Wristwatch from Polar Electro, Inc.

Another commercial vital-signs sensor that is interesting (although it uses no transmitter) is the Casio BP 100, which is a wristwatch blood-pressure sensor. The user touches the watch with a finger, and the watch measures the difference in arrival time of the pulse at the wrist versus that at the finger of the opposite hand. This is then converted into a blood-pressure reading. Unfortunately, the wearer must be well-relaxed and the readings are not accurate for certain individuals. More discussion of this is given later.

No unencumbering commercial medical telesensor exists today in the sense of a device that actually transmits data with only custom IC chips. The swimmer's device mentioned above only transmits a simple pulse rate and requires the user to wear a chest band that is not desirable for use in a combat zone. This is also true of other sports-related or exercise-related sensors, and usually the discrete-device transmitters for consumer electronics, e.g., door-opening alarms, are not designed to transmit a varying data stream. Preset-codes are, of course, easily transmitted. This occurs in the case of garage door openers and remote-control devices for televisions and VCRs. However, both the analog and newer digital cellular telephones and certain computer modems do transmit data, the former also involving a sensor (a microphone). Thus, a parallel commercial device to a medical telesensor is a cellular telephone, although they require vastly more power in accordance with their longer range and the inverse-square law. (Fortunately, there does exist a discrete-component and custom-chip combination that serves the purpose of a medical telesensor. This is discussed below.)

The Sears garage door opener circa 1980 is a good example of a low-power transmitter-receiver system with a coded signal that has been available for many years. The transparency of foliage in the utilized band is a natural benefit. Note that 902-928 Mhz is often used for cellular telephones today. Actually, a more relevant transmitter-receiver pair can be found in some of the RF remote control devices, especially those for electronics and toy cars, and in wireless home security systems. Clearly, there are many examples of commercial successes with low-cost wireless transmission, so the cost of telesensors and use even at the consumer level are not barriers.

The outstanding example of a commercial medical telesensor using some discrete components and having a small, rugged medical display monitor is the Propaq 102 from Protocol, Inc. of Beaverton, Oregon. This is analyzed in Section 3.2.

Noncommercial medical telesensors do exist, an example being the swallowable body-temperature sensor tested by WRAIR (Ped, Inc–see below). However, this medical telesensor does not use custom integrated-circuit technology and has rather obvious disadvantages. A very interesting telesensor for studies of dolphins in the open ocean has been developed by contractors for Eglin AFB. This system has dimensions of

2"X2"X0.25" and does use custom IC technology. It is especially interesting that it can be battery-powered for sufficiently long times despite the long-range of transmission necessary to this application. Since signals can only be received when the dolphins surface, and their surfacing habits are unpredictable, the transmitter must function continuously. Clearly, the much smaller transmission range and limited duty cycle of medical telesensors require vastly lower energy consumption and can therefore be powered by small batteries for many months or even years. *This establishes the feasibility of battery power for conceivable combat situations for the MIMET units with regard to lifetime energy demand.*

A telesensor developed partly at the University of Virginia's Center for Semi-Custom Integrated Circuits is typical of telesensors that currently are being investigated. Their proposed telesensor is made to sense corrosion, but again transmits only an alarm situation. They are indirectly a subcontractor on the author's project and have supplied a custom transmitter with on-board antenna at much reduced cost over previous chips such as those designed at UTK and ORNL on GaAs. Nevertheless, the cost is $4000 for the first chip from the MOSIS foundry. The GaAs 1.1 Ghz chip produced by the Instrument and Controls Division at ORNL cost $17000 several years ago. It is shown below and current work has used this transmitter except for low-power optimization considerations. This type of transmitter is especially useful for on-board implementation of a pulse oximeter due to the fact that GaAs is suitable for laser diodes.

The communications chips used in the cellular telephone industry come in sets of several chips, the telephone being required to function as a high-quality receiver as well as transmitter. The latest chip set from Rockwell is tailored to the oncoming digital transmission standard carrier frequency of 900 Mhz. The economy of scale provided thereby offers companies such as Data Critical, Inc. the opportunity to exploit the medical market for transmission of vital signs of patients to remote locations.

The consideration of carrier frequency is, of course, a basic and important question. The use of modern microcontrollers that function at very low power levels (tens of microwatts) to control the transmitter bandwidth and to signal processing of sensor data is a major reason that telesensors can even be considered. Standard circuits and software-design algorithms make it possible to use such microcontrollers in devices such as those sold by Protocol (See below.) and by Polar Electro.

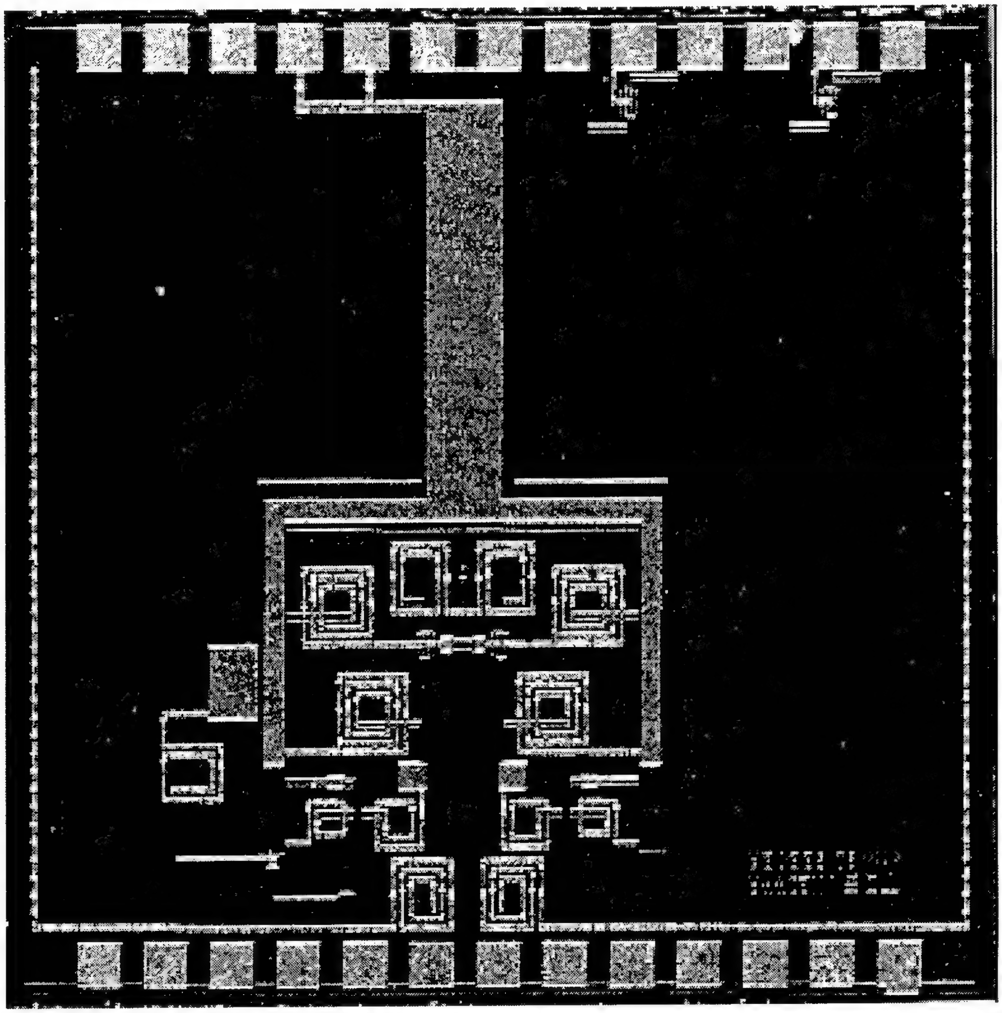


Figure 3.2. A GaAs Radio-Frequency Transmitter Custom IC Produced at ORNL for Operation at 1.1 Ghz. The use of GaAs is quite convenient for pulse oximetry, as laser diodes of the correct wavelength can be made directly on the GaAs. This circuit is currently being optimized for use at low-power levels, and has been successfully tested with on-board, thin-film lithium-ion batteries.

3.2. COMMERCIAL MEDICAL TELESENSOR DISCRETE-COMPONENT SYSTEMS AND DATA TRANSMISSION SYSTEMS

Protocol, Inc. of Beaverton, Oregon has produced a portable ECG, pulse oximetry, and blood-pressure sensor that transmits its signals. These systems are designed for ambulatory patients in a hospital, but are quite rugged. The Protocol Propaq 102 with the above medical sensors is somewhat heavy (on the order of one pound in weight) and encumbering due to the wiring harness. It transmits to a portable monitor or to a central station, and the system of sensors and portable monitor costs approximately $8800 per unit. Nonetheless, the Protocol system establishes the commercial and technical feasibility of discrete-component medical telesensors and their use in an electronically-sensitive environment. The cellular telephone industry is currently tackling the problem of use in hospitals, but the Protocol system is already widely used in a variety of medical environments. Overall, Protocol has sold 27,000 ECG monitoring systems in over 70 countries. Thus, it is clear that the much reduced size, weight, and unencumbering nature of ASIC-based medical telesensors would have a ready market.

A photograph of the Propaq 102 ECG patient-worn telesensor package without the pulse oximeter and blood-pressure telesensors is shown with a monitor in Fig 3.3 below.

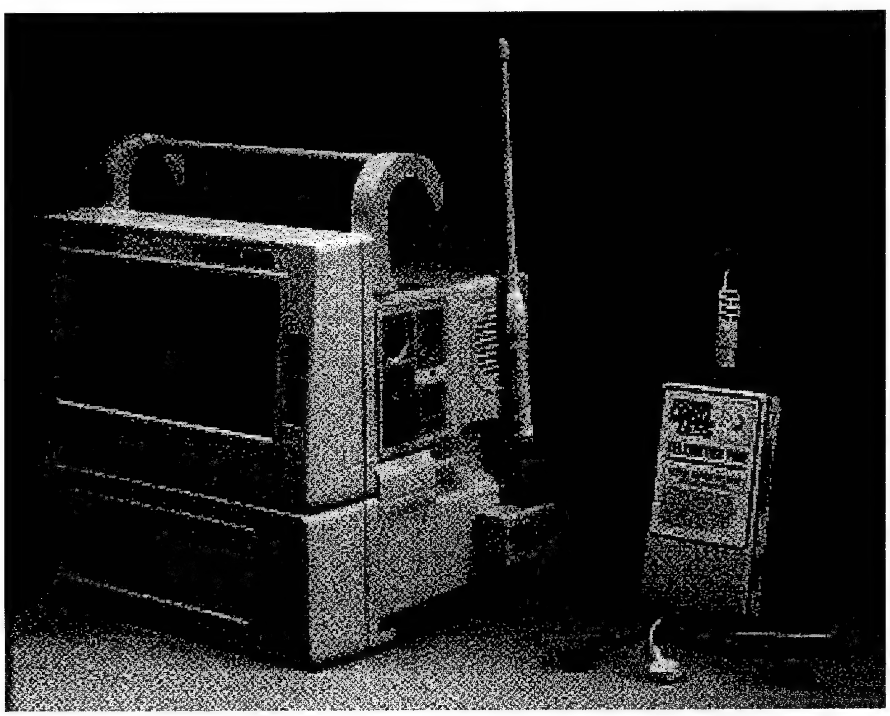


Figure 3.3. Monitor/Receiver Unit (on left) and Patient-Worn Electrocardiographic Telesensor (on right) from Protocol. This system retails for $4853. (Add about $4000 for pulse oximetry and blood pressure telesensors).

Protocol has a much smaller monitor available with a rugged package. The elimination of the wiring harness is, of course, a necessary task for the purposes of the present project, and the author has been in discussion with Mr. Larry Gray, Vice-President of Protocol, in order to facilitate technology transfer to this innovative corporation. However, the proprietary nature of the Protocol technologies has meant extended deliberations over the exact means whereby the technology can be transferred without legal difficulties. As these interactions develop, it may prove that Protocol would be a supplier of medical telesensors technology to DARPA and MRMC and this is certainly a goal difficult to achieve. The reason is that it must be done without putting competitors at a disadvantage and that is a delicate task. The publication of results in the open medical literature must be of a nature that does not divulge proprietary information, but which is in fact the vehicle for making government-sponsored results equally available to all.

Data Critical Systems of Redmond, Washington has worked with the Hewlett-Packard Corporation in the use of long-range transmission of medical data using pager frequencies (100 Mhz, 450 Mhz, and 900 Mhz) and this has resulted in the HP Palmvue system shown in Fig. 3.4 below.

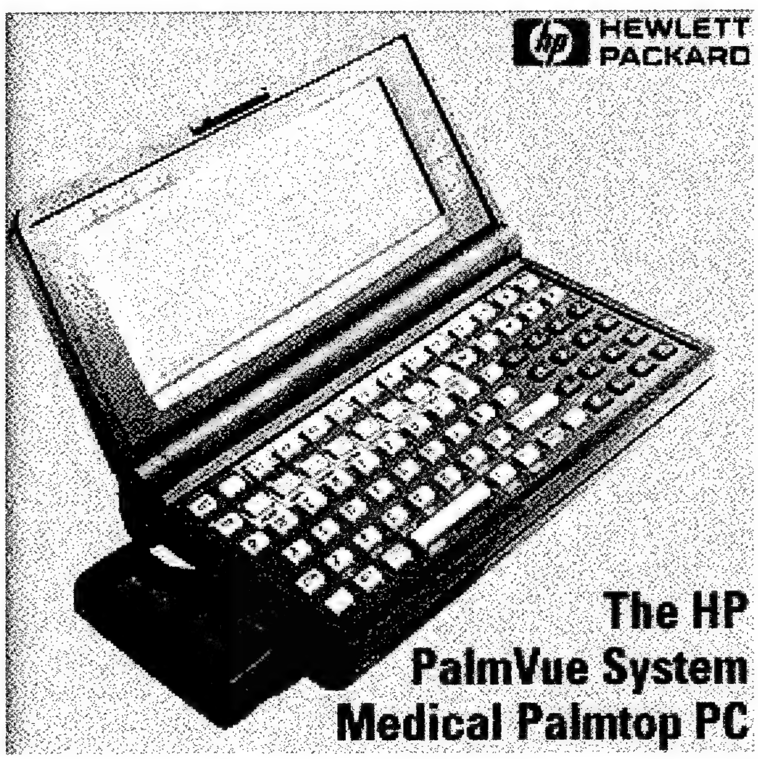


Figure 3.4. The handheld medical-data receiver and computer produced by Hewlett-Packard in conjunction with Data Critical. This unit receives data using the paging frequencies. It is capable of receiving images as well as data on patients.

A complete system, including the hospital's computers and software costs $25,000. It is useful to examine such systems because of the data encryption schemes and because they would possibly form part of a dual-use system that employs medical telesensors on individuals and transmits to medical personnel at remote locations. Recently, however, Hewlett-Packard terminated its arrangement with Data Critical and the current palmtop technology is from a Japanese corporation. The technology seems to have a reasonable future, especially in light of the upcoming Iridium satellite system deployment.

3.2. NONCOMMERCIAL, LONG-RANGE, TELESENSORS

Although medical telesensors need only have a range of 1-2 meters, it is very valuable to look at longer-range systems. This gives an indication by inverse-square scaling of the power requirements for ASIC-based telesensors. Moreover, essentially the same systems can be used except that the power supplied to the transmitter is simply reduced. While there are some unique low-power optimizations, the problem is put into a clearer perspective as the data-handling and encoding procedures are examined for commonalities. The outstanding example of such a system is offered below as the text of a web page from Eglin Air Force Base:

Begin Quote

Mammal Research Using Subminiature Telemetry (Eglin AFB)

The Instrumentation Technology Branch has developed a very small telemetry device using GaAs and Monolithic Chip Modules on the same substrate to reduce the size from 50-60 cubic inches to one cubic inch (2" x 2" x .25"). Applications for this device range from very small submunitions to very complex missile systems. Each device transmits on upper S-Band, (2310 to 2390 MHz) up to 128 digital and 64 analog channels. Depending on configuration, this device can be increased slightly in size. The 2"x2"x.25" configuration contains 4 analog, 6 discrete, and 2 digital units requiring only 1/4 watts. Built into this tiny device also is programmable capabilities ranging from frequency, transmission mode, input scaling, to signal conditioning. In order to transmit and receive data from multiple sources, a spread spectrum transmission mode has been designed and

implemented allowing transmission and reception of up to 96 units simultaneously without modification of ground receiving hardware. A demodulator is all that is needed to "de-spread" these signals. One demodulator will handle up to 24 transmitters.

Commercial and environmental applications of this technology are abundant. The Armament Directorate's Instrumentation Technology Branch is currently pursuing the use of subminiature telemetry to transmit data related to dolphin research. Before the advent of subminiature telemetry, only two or three channels of data could be collected from dolphins and was a very laborious process. First you had to catch the dolphins and attach a bulky and fairly heavy electronics package to the dorsal fin. Then, after release, 15 to 30 minutes of continuous data was collected and many hours expended tracking/locating the same dolphin to recapture it in order to remove the device and download the data for analysis.

A cooperative research and development agreement was signed with SPECTRUM SCIENCES & SOFTWARE, Inc., Ft Walton Beach to interface the subminiature telemetry device with batteries, antenna, and memory. TRI-PAL of Ft Walton Beach designed the non-intrusive "saddle-pack" to house the subminiature telemetry device, batteries, memory and antenna. Two research dolphins at the Ft Walton Beach Gulfarium are being used to design and test this saddle-pack. The saddle-pack which houses the instrumentation has been proven to stay on the dorsal fin with a series of suction cups. It is made of a modified polyethylene to form a waterproof, light weight housing shapeable vacuum molding. This is the same material used for artificial limbs. The device floats to the surface upon release after two to three days where a built-in beacon signal can be used to locate and reuse the saddle-pack. Use of subminiature telemetry allows collection of over 100 times more data for a much longer period of time. The dolphin surfaces approximately three times each minute for air at which time all the last 20 seconds of data will be transmitted to a receiver for recording and analysis. In the past, three or four channels of low data rate data was collected for 15 to 30 minutes. Now, a high data rate of 100kb/sec to 20Mb/sec, is collected on many channels and is burst out in near time. This type of data has never been available prior to subminiature telemetry and

the efforts of the Instrumentation Technology Branch. Valuable data can be collected and correlated to events leading to a better understanding of the impact that our environment has on dolphins and endangered species.

Dolphins are being used because of their availability at the local Gulfarium and experience that man has working and training them. The long term goal is to apply this technology to monitor global warming and its affect on the blue whale and sperm whale all of which affect the services and mankind. Since the dolphin represents one of the worse case scenarios, future work with endangered land animals will be much easier.

Subminiature telemetry provides a unique opportunity to apply an advanced technology developed for weapon system development for research in an area that will affect our environment. Research with the dolphins is just a starting point to use this technology for environmental applications. As the techniques are developed and data is collected, we gain a much better understanding of how we impact other parts of our environment and the world that we live in.

For additional information, please contact Mr. Ed Keller, (904) 882-2220, ext 1288 or send e-mail to...

KELLER@EGLIN.AF.MIL

End Quote

SOURCE: http://www.wlmn.eglin.af.mil/public/mammal.html

Unfortunately, the high cost of GaAs wafers when completed are prohibitive for wide-scale use of any GaAs ASIC. The possible application of the above developments in medical telesensors, while not considered in the quoted text, is certainly clear; the use of multiple data channels, for example, is demonstrated from 100 Kb/s up to 20 Mb/s. This is further evidence of the ASIC advantage in telesensors, and establishes the feasibility of sending substantial diagnostic information in a very brief interval. This is particularly important for medical telesensors in the modern combat zone where electronic signatures must be minimized in time. While the gallium arsenide technology used in the above project is

prohibitively expensive for widespread applications, there are some applications which might be enabled by the GaAs telesensors, but modern advances with doped silicon will in all probability make this a moot issue. Silicon-based transmitters extending to 2.45 GHz are quite likely by 2000 or in late 1999. These are further described in the next Chapter and are a consequence of the needs of the computer industry to provide short-range communication between computers and peripherals.

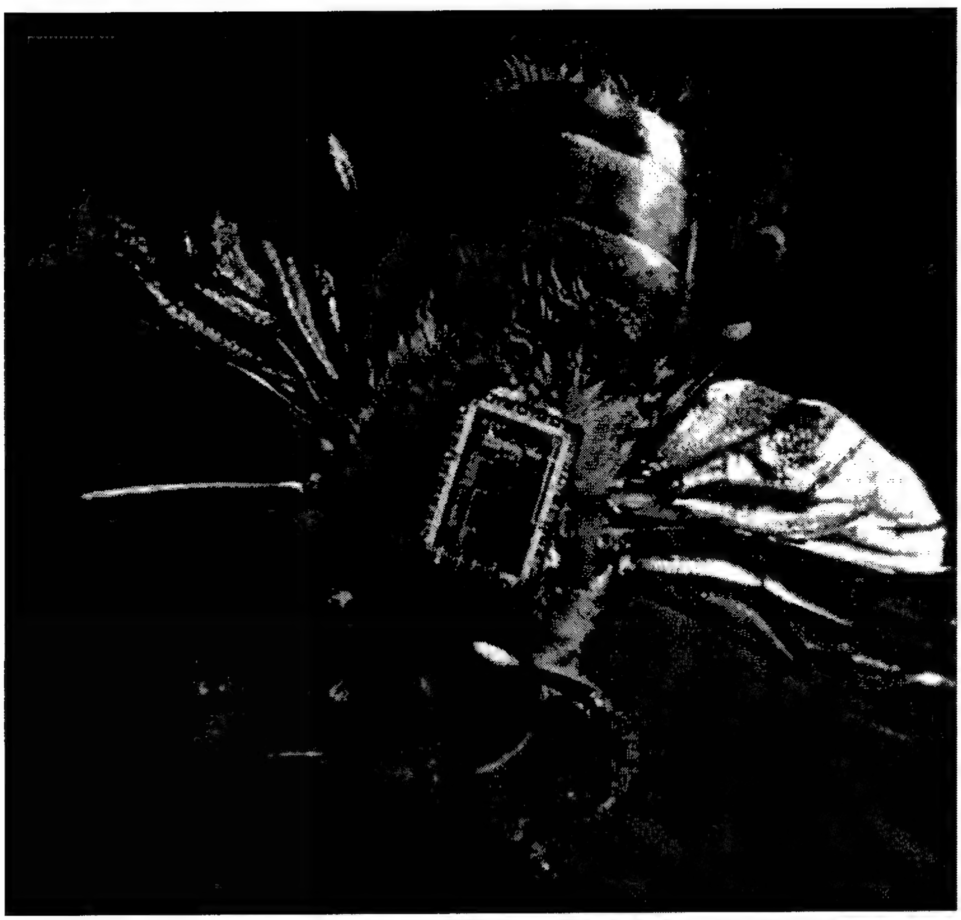


Figure 3.5. The Gallium Arsenide 1.2 GHz transmitter of Fig. 3.5 shown mounted on a honeybee. This permits the tracking of the bee for agricultural purposes. The chip uses on-board solar power cells, a ring oscillator in lieu of a crystal, and an on-board antenna. As with all gallium arsenide ASICs, the cost of this device is prohibitively large for most applications and the technology will soon be surpassed by use of new doping methods for silicon. The silicon-based transmitters are far less expensive and will be produced by the computer industry at consumer levels of production quantities.

3.4. BODY-TEMPERATURE TELESENSORS

Perhaps the easiest medical telesensor to construct and one of the most valuable physiologically is that for measuring body temperature. It can be referenced internally to a constant power dissipation by a resistor or it can be designed with bipolar transistors to produce the absolute temperature; it can easily be powered with on-board, thin-film, lithium-ion batteries, and is therefore completely self-contained; and, it can be made in a size that is a few tenths of a millimeter thick and is on the order of 2x2 mm square or even less. Finally, it can be enclosed in a thermally partially insulating coating so as to give a temperature reading that equilibrates to the body temperature and does not change rapidly with external influence.

In assessing the cost of a body-temperature telesensor, there are some similarities with commercial chips. The Analog Devices AD590KH is a commercial temperature sensor on a chip that produces a signal of 1 microamp per degree centigrade. It is a small, electrically insulated, hermetic package and it has excellent linearity. It works from -55 to +125 C and costs $10 to about $70, depending on absolute accuracy at 25C. Interestingly, it can be remotely located hundreds of feet from the readout device using twisted-pair wiring, since it is a current source device. One can easily observe 0.01 C changes with this sensor, and the addition of a transmitter, antenna, battery, and voltage-controlled oscillator on the chip would not add significantly to the cost.

Ped, Inc. has produced a the receiver (the most difficult part in this case) for a temperature telesensor "pill" that was used by John Glenn during the recent orbital flight of NASA's space shuttle. It is sold by HTI Technologies, Inc. See

http://www.htitech.com/

and

http://www.pedinc.com

This device works by using a vibrating quartz crystal with a resonant frequency that changes as a function of temperature. The crystal vibrations cause magnetic field variations in a nearby coil and these are detected by the external receiver, which is quite extraordinary. The device is quite sizeable and naturally is only for temporary use. However, it has achieved a degree of commercial success.

Biomedical Data Systems, Inc. has produced a short-range temperature/activity telesensor and has patented a transponder for queries of body temperature and other vital signs. The system is small and is packaged in an injectable capsule. However, the transmitter is amplitude modulated (AM) and has a number of difficulties. It's main application is monitoring of laboratory mice. See

http://www.bmds.com/

A.J. Woakes of the School of Biological Sciences, University of Birmingham, Birmingham, England has developed an ASIC-based device for logging of body temperature in animals. While not useful for human subjects, this device demonstrates the feasibility of long-term monitoring electronics, particularly with regard to power requirements. See

http://smub.st-andrews.ac.uk/biomedtelem98/woakes.html

Invocon, Inc. has a spread-spectrum transmitter with a temperature sensor, but the system is roughly the size of a stack of five U.S. quarters. This is certainly far too large for most uses. A number of similar devices are currently on the market. They utilize "off-the-shelf" integrated circuits, install custom programming and linkages and connect and package them. Another system of similar technology can be viewed at

http://www.atstrack.com/Products/ATS_Framed_Transmitters.html

Sarcos, Inc., which was responsible in the main for the Personal Status Monitor has not produced any widely used product and relied to a significant degree upon commercially available monitoring devices. The "wristwatch" concept has several drawbacks, not the least of which is that it only measures skin temperature and the readings are affected by the ambient temperature. A considerable drawback is the lack of sufficient redundancy such as is available in a distributed system on the body. However, much can be learned from the work done at Sarcos, Inc. and there were a number of benefits obtained for researchers in this field.

Within a given area or building, the company VitaLink, Inc. has a telemetry system for vital signs, including temperature, that permits compatibility with a broad range of commercial monitoring systems. See

http://www.vitalcom.com/healthcare/products/vlink/vlink.html

Complete wireless systems for vital signs are, of course, widely available for hospitals. Siemens, Inc. and Hewlett-Packard, Inc., both have such systems installed in a number of hospitals. However, none of these systems are appropriate for use in the combat zone due to the size, weight, bulk, and expense considerations on balance. And are certainly not within the range of economy demanded for home healthcare.

In summary, computer simulations and chips produced thus far show that the hardware for a body-temperature telesensor can in fact be economically produced in an extremely small, self-contained package. Scheduling depends upon funds arrival dates and foundry schedules in a research and development effort, but the primary tasks are related to optimization for high-volume production.

A key requirement for the military combat zone and for many civilian applications is that the transmission of the temperature and other vital signs be secure, noninterfering, and operable in noisy electronic environments. This requires the use of spread-spectrum radio transmission with a large number of spreading segments. The lack of this technology is one of several reasons why most commercial systems used for animal monitoring are not useful for the desired medical applications. A brief introduction to spread-spectrum is given below.

SPREAD SPECTRUM RADIO COMMUNICATIONS

What is Spread Spectrum? There are many ways of extracting a signal from a noise background even when the noise exceeds the signal in intensity so long as the receiver is not saturated. All of these techniques rely upon electronics that recognize certain signal characteristics. For example, if a message is constantly repeated at known intervals, the receiver electronics looks for anything that repeats itself with the given periodicity. Similarly, the receiver may use phase information to extract what it seeks from the generally random noise. The technique associated with spread-spectrum radio transmission is unique in that the signal looks like pseudo-random noise to an uncorrelated receiver. In essence, spread-spectrum means that the signal is spread out across frequencies to a much greater extent than the bandwidth required for the transmitted information.

The receiver is programmed to examine the bandwidth of the spread signal, and correlate the data (despread it). The process of correlation also causes any other signals received to be spread as the actual signal is de-spread. This causes spurious signals to be

reduced to low-level noise. The result is a signal that is extremely difficult to detect, does not interfere with other services, and still passes a considerable bandwidth of data.

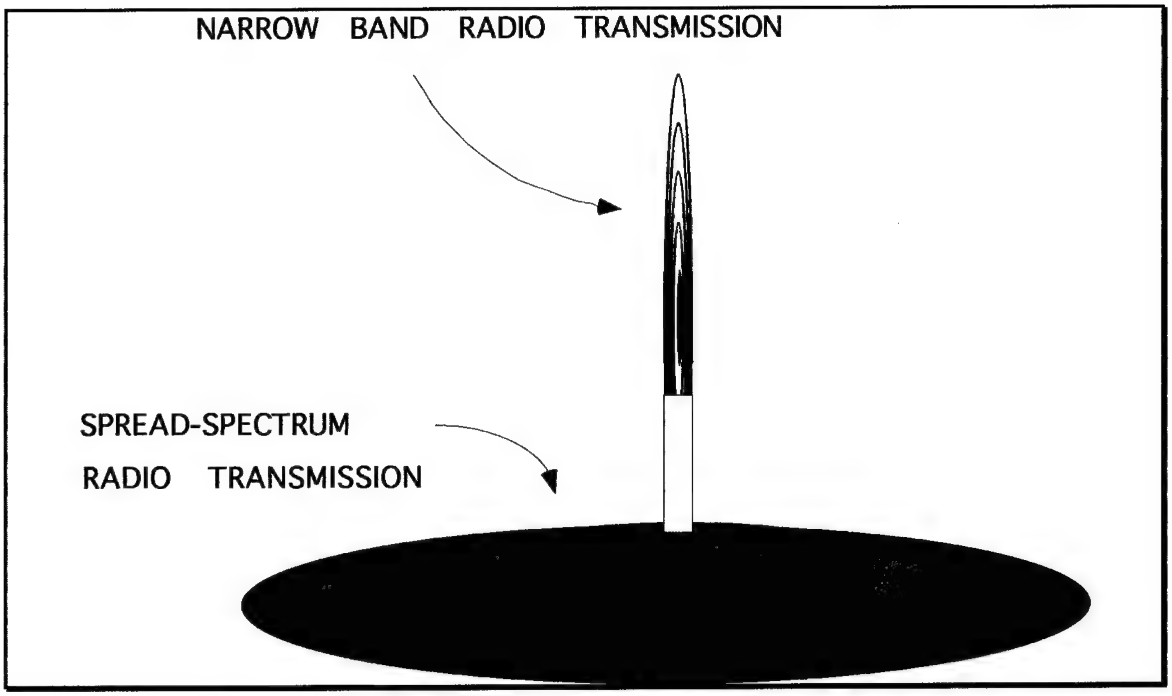


Figure 3.6 Spread Spectrum Signal Compared with Conventional Narrow-Band Signal. The spread-spectrum transmission extends over many frequencies and looks like low-level noise (lesser intensity than the normal background noise) to any receiver not correlated with the transmitter.

The ISM Band. Certain commercial, personal-use, radio transmitters communicate in the 915MHz Industrial, Scientific, and Medical (ISM) frequency band, which spans the frequency range of 902–928 MHz. Within this band, the radios use spread spectrum signaling (Figure 4.1).

Spread-spectrum radio transmission was originally developed by the military to attain reliable, jam-resistant communication in the combat zone. Part 15 of the FCC regulations of the late 1980s allows civilian spread-spectrum radios to transmit in this band with up to one watt of power with up to a 6 Db gain antenna without requiring that the operators have radio licenses. Higher gain antennas may be used, with a corresponding reduction in transmission power. Many of the highly efficient spread spectrum radios for wireless communications of computer data operate to provide reliable, noise-resistant, data transfer while maintaining secure communication using only 250mW of RF power. By comparison, cellular telephone transmission levels (in the 800-900 Mhz frequency band) are 600 mW (0.6 watt) for most hand–held units, and three watts for transportable and vehicle–mounted units. The lower RF power in spread-spectrum radio offers longer battery life and less co-channel interference in MicroCellular-like configurations. With appropriate outdoor antennas, and line-of-sight conditions, 40-mile paths are possible with some types of spread spectrum radios.

Spread-spectrum radios communicate by spreading the signal pseudo–randomly throughout a given range of frequencies, this requiring in specific cases a shift register. This is very different from conventional FM (Frequency Modulation) signaling used for radio, television, and packet radio services (such as Ardis). With simple frequency

modulation a signal is transmitted at a fixed carrier frequency licensed to an individual user or specific class of users, and the carrier is modulated about this fixed frequency to provide the information content. This provides a relatively narrow transmission bandwidth and preserves nearby frequencies for other signals.

By spreading the same signal energy over a wider range of frequencies, the signal becomes more dilute. It is then more difficult to detect, and hence is more difficult to jam by either hostile interference or the presence of background RF noise. This signal also presents less interference to other users of the same frequency band. It is this noise resistance and the ability to have many different devices operating with minimal co–channel interference in the same band that makes spread spectrum a superior radio technology for telesensors. For optimal noise immunity, jam resistance, reliability and power conservation, new radios employ a technique for spectrum spreading called "direct sequence" spread spectrum. Another common technique for spectrum spreading is frequency hopping. Both are discussed below to offer a better understanding of the tradeoffs available in this technology.

Direct Sequencing versus Frequency Hopping. As its name implies, frequency hopping is accomplished by periodically changing the frequency used to transmit data bits. Every few milliseconds, the transmitter changes the frequency used for transmission, and the receiver, which endeavors to remain synchronized to the hopping sequence, tunes to the next expected frequency. During each hop, the frequency hopping radio uses conventional, narrow band radio techniques to transfer the information. During transmission, frequency-hopping radios send one or more data packets on each frequency between hops. (The typical “slow hopper” sends many packets on a single hop, which can last up to 400 ms.) At each frequency, the “spread spectrum” signal of a frequency hopping radio is not actually spread, but instead looks essentially the same as a conventional radio signal broadcast at a fixed frequency.

The direct-sequence spread-spectrum radio spreads the outgoing signal across the entire band or channel of operation, so for each transmitted data symbol, components of the signal concurrently occupy many different frequencies. The radio typically concurrently spreads each bit across 9-14 different frequencies (Figure 3.7).

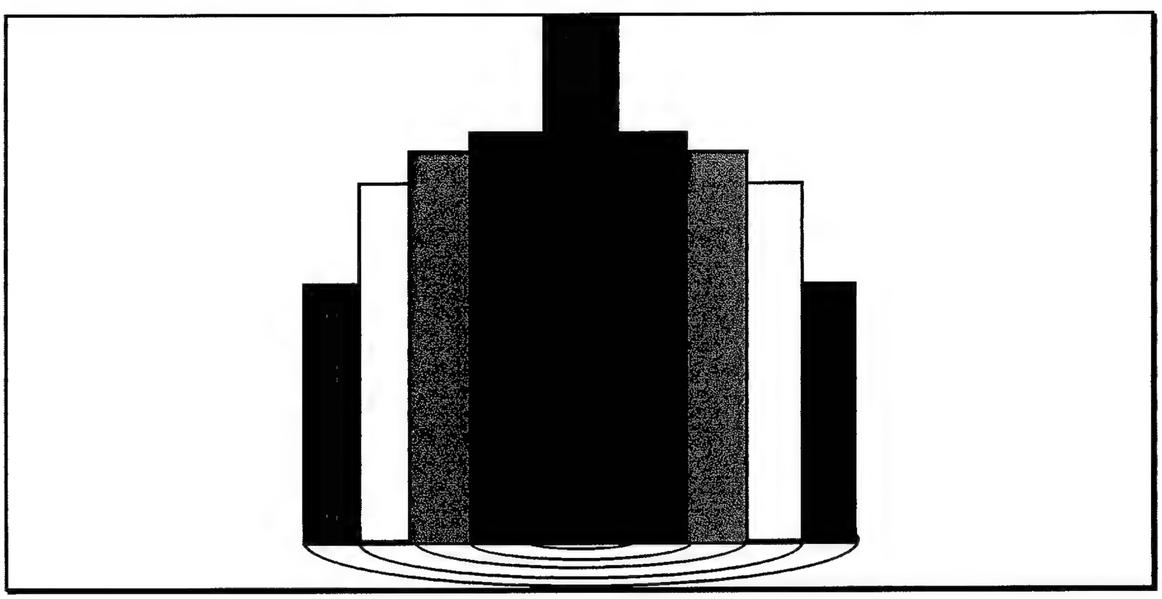


Figure 3.7 A direct sequencing radio concurrently transmits at many frequencies.

CHAPTER 4

RESULTS OF THE PROJECT

4.1. BACKGROUND REVIEW

THE TECHNOLOGY IN BRIEF

Medical telesensors are application specific integrated circuits (ASICs) which can measure and transmit physiological vital signs over a very short range (typically 2.5 meters or less). In recent years it has become possible for small research programs to design ASICs with desktop computers and then to obtain fabricated chips in low quantities from various fabrication foundries.[1] This is a somewhat more difficult process for medical telesensors due to the fact that both analog and digital electronics are necessary. But quasi-monolithic forms were fabricated in this program at Oak Ridge National Laboratory (ORNL) and the University of Tennessee at Knoxville (UTK) sponsored by the Defense Advanced Research Projects Agency (DARPA) under an MRMC contract. Also, a collaboration was established with the University of Tennessee Medical Center at Knoxville (UTMCK) and Yale University School of Medicine for future testing. In this project we were able to produce a preliminary form of a temperature telesensor of 9 mm^2 size, although external components were needed since the design models were not fully developed. Improved design models were obtained as a result of this work and a self-contained prototype can now be fabricated within months. The preliminary ASICs were functional and the temperature was transmitted in noisy and sensitive electronic environments using direct-sequence spread-spectrum, radio transmission in the medical band (902-928 MHz). This ASIC is further described below. Other medical telesensors of earlier stages of development are also described. Concepts for dual use are displayed in part in Fig. 4.1 and Fig. 4.2.

IMPACT AND NEEDS ADDRESSED

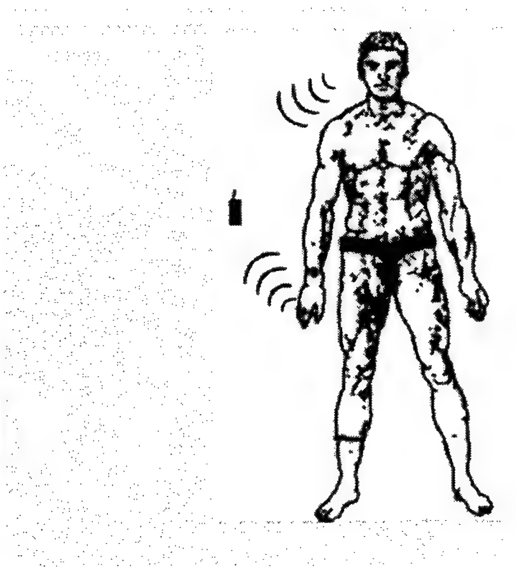
The measurement and reporting of physical and chemical vital signs currently involves expensive and bulky equipment, wires, labor for attachment and verification of results and performance, and manual recording, reporting, and archiving. The monitoring is typically done infrequently as individuals are admitted to hospitals or clinics or is

carried out only for physical examinations. Transport of patients is hindered, there are extra precautions needed for electrical isolation, and there remain a large number of analog systems in use with attendant high labor costs. The average hospital in the United States was spending a half million dollars annually on pulse oximetry alone in 1994.[2] Most of this could be attributed to the labor costs as attachment, reattachment, manual monitoring, archiving and other tasks were carried out.

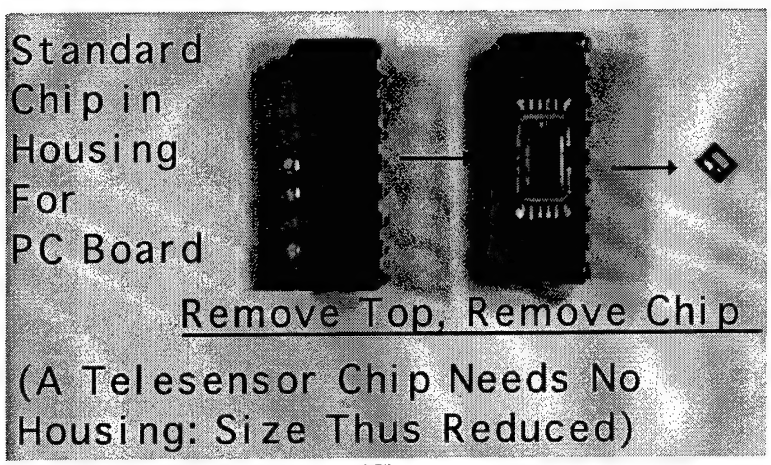
Patients monitored within the hospital suffer from limited mobility during wired monitoring and often must be periodically awakened during the night for the taking of temperature and other vital signs. In some cases, a blood-pressure cuff is worn and inflates periodically while the patient is attempting to rest. In intensive care wards there is on occasion confusion concerning the wiring. This results in complete removal and reattachment of all wires. Preparation for emergency surgery is hampered and signals are not available during transport and while reattachment is made.

For chemotherapy patients who lose the ability to regulate body temperature, a thermal blanket or ice bath is used to chill the body in reaction to a fever. This is a costly and highly uncomfortable procedure. However, a fever that is detected at onset can be managed with medication and this could be accomplished using a temperature telesensor.

The "golden hour" for casualties in the military combat zone is the period in which 70% of fatalities occur. The use of medical telesensors was devised primarily to address this issue by providing earliest possible communication and assessment of condition. The large number of dual uses is to be expected and is a clear benefit of the funding for military use.



(A) (B)



(C)

Figure 4.1 (A)-(C). Concept and Use. In (A) two preliminary (uncompensated) temperature telesensor chips are shown on a finger tip. In (B) the application to patient monitoring is sketched showing two of several telesensors transmitting regularly to a receiver unit. In (C) the size reduction obtained by making the telesensor self-contained is shown relative to standard chip packaging used when chips must be interconnected on a printed circuit (PC) board.

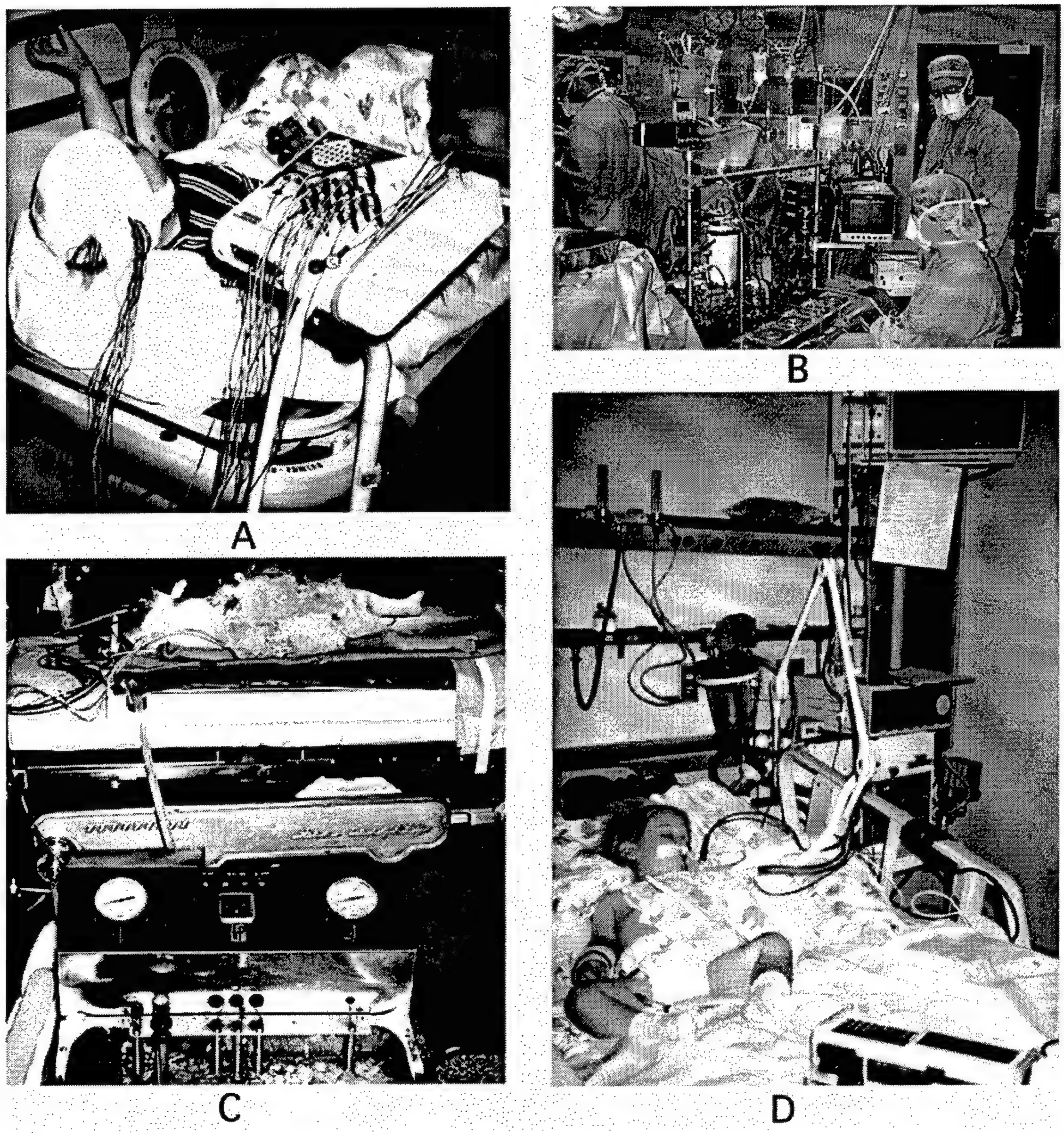
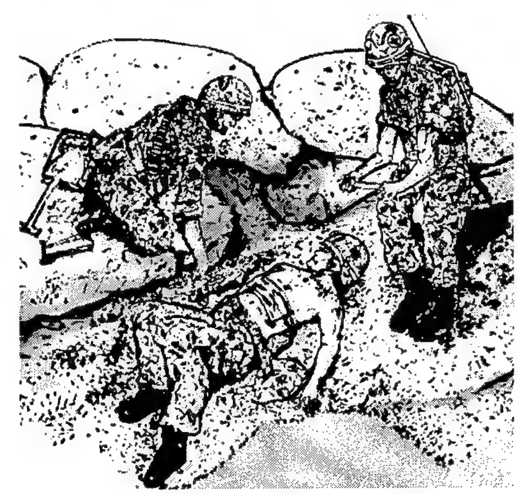


Figure 4.2 (A)-(C). Civilian/Dependent Applications---Illustration of Needs for Inpatient Examples. In (A) a large wire bundle is being used in performing an EEG. Telesensors can eliminate the external wire bundle completely. In (B) a modern surgery is shown to illustrate the present complexities. In (C) a cancer patient is shown in an icebath (See text). In (D) a child is being monitored in an intensive care unit. As in (B), there are many complexities, most of which cannot be eliminated. But telesensors can be used to eliminate the pulse-oximeter wires and the electrocardiograph wires and can add automated temperature and blood-pressure tracking and recording.

The inherent inaccuracy of aurally inserted, hand-held digital thermometers has been documented[3] including the cases of clinical instruments. Such inaccuracies can be dangerous, but core body temperature is not easily monitored even with internal readings such as are provided during cardiac and neurological surgery where esophageal and bladder readings are extrapolated to determine the temperature of the hypothalamus.[4]

There are presently no provisions for inexpensively providing baseline data on vital signs for most individuals prior to hospital admission. For the general population there is no database such as might be provided by long-term monitoring and which might be used for diagnostics. In emergency situations the lack of baseline data reduces the physician's ability to rapidly determine the optimal treatment. Illustrated at left is a medic reading vital signs on a hand-held receiver/display unit. An injured warfighter's vital signs would be immediately available and recorded from a telesensor system. Currently it requires 45 minutes for attachment and signal acquisition of vital signs for evacuated casualties and the data trending from the time of injury is not available. The telesensors would remedy this and would provide the baseline data needed for comparison with the data observed by the surgeon.

Despite the clear concerns for the most hazardous occupations, including service in the military combat zone, firefighting, police work, high-voltage line repair work, and certain construction work, there are few if any provisions for long-term or even on-duty monitoring of vital signs. In other hazardous occupations, including aircraft pilots and long-distance truck drivers, there is no medical provision beyond a physical examination.



As the population peaks of the post-war generations produce peaks in the demands for healthcare in the next decade, medical services will suffer an extraordinary

challenge that cannot be adequately addressed by a continuation of the present technologies and their associated labor and instrumentation expenses.

The use of ASICs should alleviate the weight burden of military medics as alternatives become possible. This issue is critical to the ability to deliver earliest possible aid. With early notification and with increased mobility, fatalities can be reduced.

4.2. RESULTS IN BRIEF

FINAL STATUS

We have developed and tested medical telesensors for temperature and for pulse oximetry. Testing used commercially available, mechanical, physiological models which permit accurate simulation of physiological structure and vital sign signals over a wide range. Our spread-spectrum transmitter and a transistor-based temperature sensor have been combined on a single chip, although external components are now needed due to the trial status of the mixed-signal components. Other than the temperature telesensor ASIC, discrete systems needed for study prior to implementation of ASICs were devised which measure and transmit vital signs such as pulse waveform, arterial oxygen saturation, and blood pressure.

We presently also have wireless electroencephalographic (EEG) and electrocardiographic (ECG) systems composed of commercially available integrated circuits and discrete components. We also have constructed a discrete-component receiver unit interfaced to a laptop computer. Our ASIC was tested to show that it can transmit temperature via spread-spectrum radio frequency (RF) with an accuracy of 0.1 C^{o} over a range of 50 C^{o}. Further details are discussed in the Technical Discussion.

WORK ON TELESENSORS

For the telesensors we were able to take the temperature telesensor to full prototype. We then attempted to use the same transmitter and add it to an ASIC-based form of our pulse-oximeter that we developed to prototype level. With our current modeling corrections, an additional fabrication run would eliminate the need for external compensation and would permit placement of the temperature telesensor well within the

aural canal near the tympanic membrane. Placement systems are designed for this purpose since the desired temperature reading should be very close to the temperature of the hypothalamus. A successful collaboration with physicians has demonstrated accurate vital signs using physiological simulators. An application for use on human subjects will be filed and an appropriate revised plan submitted if further work is performed, but the project work did not involve human subjects.

RECEIVER/DISPLAY UNIT (EXECUTIVE UNIT)

Signals in our presently designed telesensors are transmitted over a range of up to 2.5 m to an executive unit for display, and interfacing to a computer (as a PCMCIA card). The executive unit eventually could assume different forms for different applications---it might be a simple receiver/display/alarm unit, or it might contain a microprocessor and memory for queries of a telesensor array, analysis and recording of the data, and it might also be interfaced to the pager network since this now permits transmission of vital signs via a system from Data Critical, Inc. A long-range transmitter would be appropriate to military applications in the combat zone. The executive unit could be worn on the body or placed at bedside, and could be attached to graphical displays. The designs in hand would permit economical fabrication of any of several forms. This unit would replace our preliminary receiver in any follow-on project.

BATTERIES

Our concept was to produce externally controllable, externally rechargeable, self-contained ASICs of a few millimeters in size in all dimensions and which require no housing or external connections to a printed circuit board. We have worked with Dr. John Bates of the ORNL Solid State Physics Division who has developed advanced, thin-film, rechargeable, lithium-ion batteries with four times the energy density of current lithium-ion batteries. We are currently working with a private company that has produced button cells based on this advance. Battery lifetime between recharges are on the order of several weeks depending upon duty cycle, but typically could operate for longer periods if programmed to transmit only if pre-determined changes occur.

It would be expected that our results would be much less costly than presently used monitors in high-volume production and would be within the range of home healthcare uses. The executive unit would be the most costly component, but prices of handheld and laptop computers continue to fall with time even while producers add increased capabilities and reduced size. Health insurance companies might be disposed to pay for this unit for home healthcare throughout the military and civilian communities if the monitoring system provides the economic advantages which may be assumed by conversion of discrete-component systems to chips. The systems would permit long-term monitoring, automated reporting and archiving, and reduced healthcare labor and equipment costs. Secure maintenance of patient identification for the data gathered is a natural consequence of the use of the telesensors. The digital nature of the transmitted data permits rapid analysis and display in novel ways. For example, wavelet transforms can be quickly displayed as colored plots which quickly reveal the important frequencies of signal waveforms as a function of time. Phase-space plots for analysis by chaos theory and nonlinear algorithms are currently available for the analysis and display of vital signs on both laptop and palmtop computers. Hence, we expect that the presently designed form of the executive unit is appropriate for several applications.

PHYSIOLOGICAL TESTING

Currently we have established a route from R&D and engineering, through clinical trials, and field trials following the two-year development effort. Clinical testing could be done at the Walter Reed Army Institute of Research (WRAIR), the University of Tennessee Medical Center (UTMCK), the University of Alabama, Birmingham (UAB) Medical Center (previous funding for our initial work on medical telesensors was given through the UAB Research Foundation), Vanderbilt Medical Center and at Yale University School of Medicine. Field tests also would be conducted with the Emergency Medical Services (EMS) of Hancock County, TN a rural nearby county and with the EMS of UTMCK. Collaborations with Dr. O'Brien of UTMCK and Dr. Bogucki of Yale would specify both civilian and military medical requirements if this project is followed by additional funds in the future. The joint efforts using physical models might be supplemented with cadavers for mechanical testing with regard to possible penetration of

the tympanic membrane. This option is currently being explored, but only physical simulation has been done at this point and was necessary in any case in order to simulate a wide range of signals.

4.3. TECHNICAL DISCUSSION

Each telesensor contains a sensor for one or more physiological vital signs, two analog-in channels with 10-bit analog-to-digital (A/D) conversion electronics and sampling at 100 kHz, signal processing, response/coding circuits, a voltage-controlled oscillator and phase-locked loop, logic circuits, an RF mixer/modulation electronics, other data transmission related circuits, a controller receiver, a crystal, an antenna, and a battery (the latter three being borne on a bonded substrate or other suitable mount depending upon test results). Transmission is via spread-spectrum, on-board, radio-frequency (RF) transmission in the medical band (902-928 MHz) using direct-sequence spread-spectrum. Transmissions are detected, analyzed, and monitored or re-transmitted over longer range by the nearby executive unit in the various forms that can be developed from our initial form. Local transmission is uniquely coded and operable in sensitive and noisy electronic environments since the 63-segment spreading permits much greater versatility in this regard than the spreading used in communications requiring high rates of data transfer. For example, the current IEE 1394 standard for wireless ethernet uses only a three-segment spreading and is vulnerable to microwaves from consumer devices.

In Fig. 4.3 we show a preliminary temperature telesensor that was designed by a graduate student supported by Dr. Ferrell's project funds. This chip contains a simple AM transmitter and has the antenna on board. The design was convenient for testing the concept and the temperature circuit (PTAT[5], or "proportional to absolute temperature"). Fig. 4.4 shows the computer-generated artwork for a portion of the electronics with the various portions labeled.

However the high losses introduced by placing the antenna on silicon, and the fact that a ring oscillator used in lieu of a crystal produced large frequency drift, pointed the way to a substantial redesign. The redesign effort was carried out over a period of nine months. The new design allows the antenna and a reference crystal to be produced on

quartz or on a glass-imbedded Teflon substrate that can be bonded to the silicon. Further, the carrier substrate provides the opportunity for deposition of a thin-film Li-ion battery. The substrate can then be bonded to the electronics.

A 0.5 micron process was chosen for the new design in order to further reduce the size of the chip and allow for several additional features. An optical (infrared) receiver was later added to permit programming of the duty cycle and an entirely different transmitter was designed. The programming unit was tested and is as simple to use as a television remote control unit.

Since operation in noisy and sensitive electronic environments is highly desirable, we replaced the AM transmitter with a 63-segment, direct-sequence, low-power, transmitter. This work involved a team of several investigators from two divisions and the results obtained with the fabricated chip were recently presented.[6] The computer generated artwork for the first beta model temperature telesensor is shown in Fig. 4.5. The RF output level is –20 dBm to –1 dBm nominal into a 50 ohm load. The data burst rate is selectable 130 Hz to 0.125 HZ in binary steps. The nominal chipping rate is 895 kHz/n. The analog-to-digital conversion is 10 bit and there are four analog-in channels. The 0.5 micron process allows use of 3.3 volts for the battery and the system draws 24 ma at the maximum data burst rate. This drops to 2.15 ma at the minimum rate, but the transmissions need not occur unless there is a temperature change. Sudden battery drain is prevented by trickle charging a capacitor that fires the transmissions. The beta-2 chip (Fig. 4.6) contains a serial interface for programming of on-board functions. It has identification coding and a formatting logic block. It is compliant with emerging IEEE "smart sensor and actuator" standards and we are a participant in setting these standards.

The beta temperature telesensor shows the feasibility of medical telesensors and is a basis for further medical telesensors. Our custom design libraries have been improved and the transmitter can be completed except for optimization for high-volume production. Work possible in the future includes added iterations for fabrication of the temperature telesensor and the receiver for the executive unit and development of the pulse oximeter telesensor ASICs. The latter also provide measurement of blood pressure via pulse velocity and waveform characteristics. These may be analyzed from the pulse oximeter or an accelerometer-based pulse monitor. The latter offers advantages under conditions of

low blood pressure or shock. But pulse oximetry does not require measurements on the extremities (where such difficulties are most evinced) if the device is sufficiently small.

New polymer batteries are expected in 2000 that offer ten times the amp-hours of present batteries. Our current designs, while useful in many situations, would benefit as new technology becomes available. Applications such as shown in Fig. 4.7 would be possible within two years. Our pulse-oximetry work[7] should similarly benefit since the power demand of the light-emitting diodes is particularly large. With the upcoming battery technology we would be able to increase the duty cycle of the pulse oximeter without reducing the time needed between recharges. New and more efficient light-emitting diodes will also become available during the follow-on project period and could readily be incorporated into our models and hardware. We are actively seeking funds to complete this project.

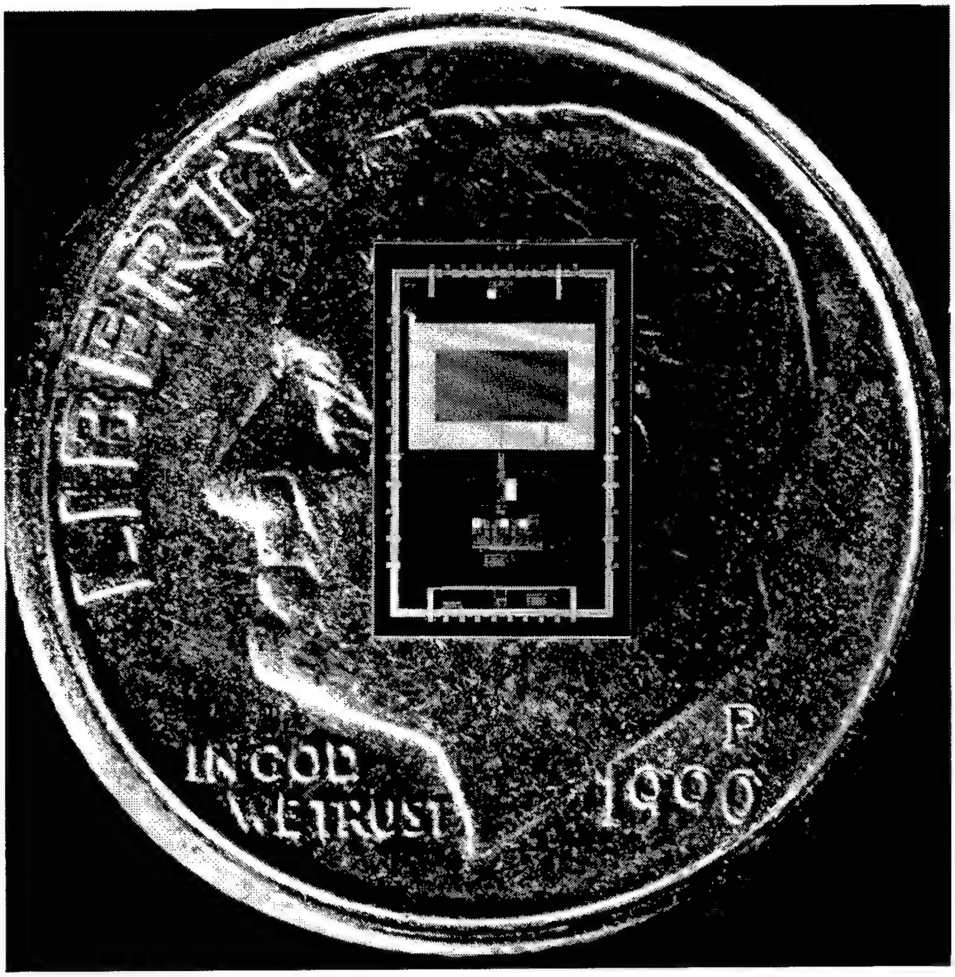


Figure 4.3. Initial (alpha model) temperature telesensor produced using a Bi-CMOS process at 2.0 micron linewidth. This model produced accurate absolute temperature readings and provided the impetus to develop a substantially more sophisticated model. The folded-slot antenna seen as the large rectangular area in the upper part of the figure was designed with elementary analytics, but has since been optimized using a finite-difference time domain (FDTD) analysis program written by one of the proposers (Dr. Thomas Ferrell, author). However, the losses due to the antenna being directly on the silicon substrate caused excessive power demand.

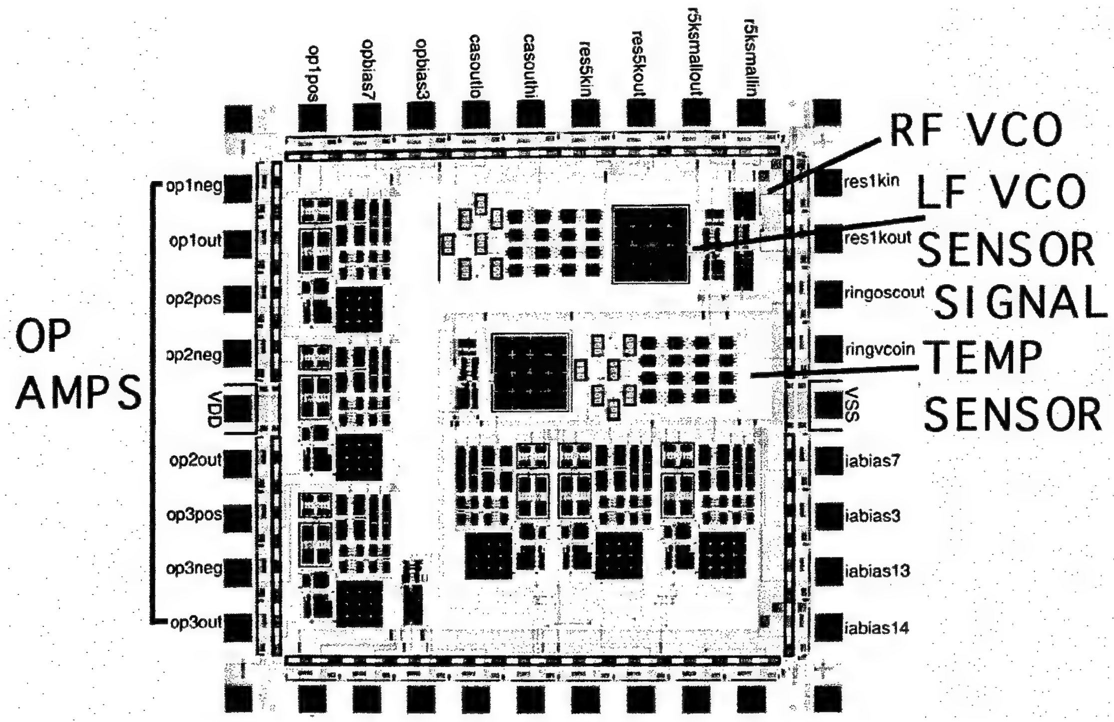


Figure 4.4. Computer generated artwork for the alpha model temperature telesensor. The transmitter was designed for operation at a carrier frequency of 300 MHz (which permits penetration of foliage), and the simple AM operation permitted inexpensive fabrication. Some redundancy was used on the chip due to uncertainties in the analog models. This design was the subject of a Masters thesis by Mr. Zaid Salman. Dr. Alan Wintenberg of ORNL provided the operational amplifiers and the system specifications were provided by the proposer. While transmission across a range of up to 10 meters was successful, the power requirements were deemed too high and the frequency drift excessive. This design won first place in a national IEEE competition among student ASIC designers.

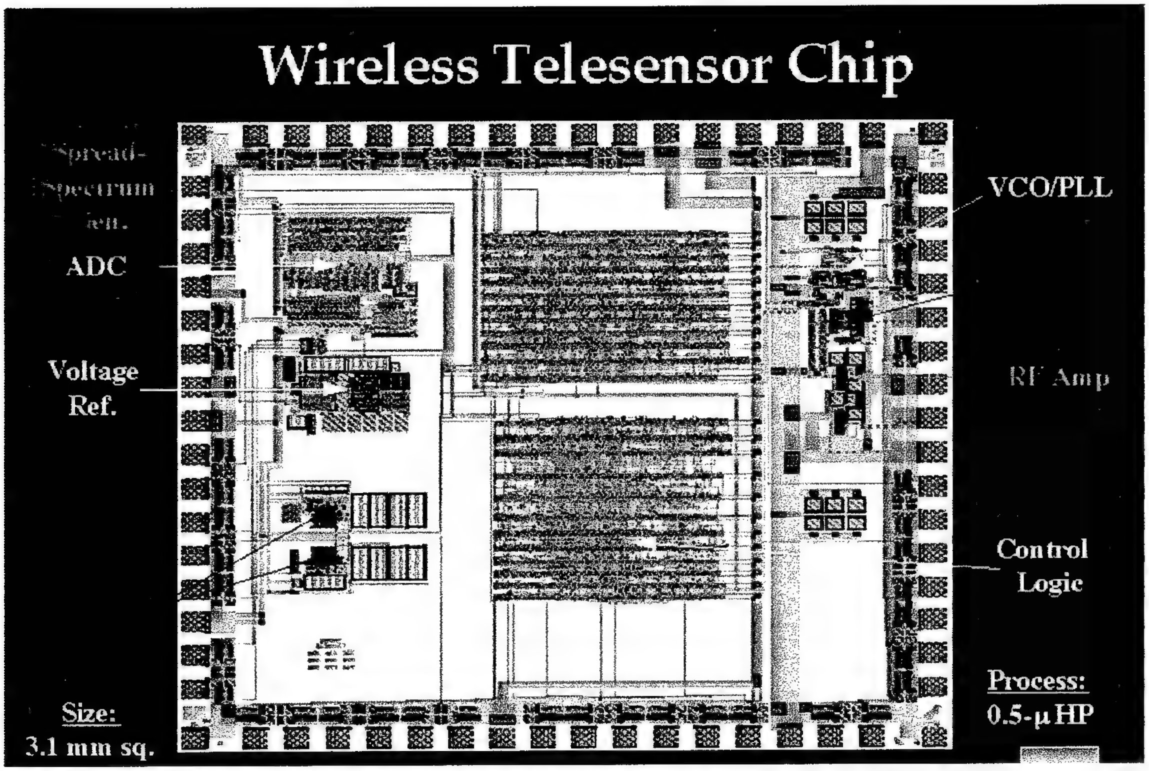


Figure 4.5. Beta-1 version of the temperature telesensor ASIC. This version uses direct-sequence, spread-spectrum, radio transmission in the 902-928 MHz band. Features are produced at 0.5 micron linewidth. The large portions in the center right are logic circuits, but the temperature sensor is an analog PTAT circuit. There are four analog-in channels with 10-bit analog-to-digital (ADC) converters. VCO in the figure stands for the voltage controlled oscillator, while PLL stands for the phase-locked loop. The sensor has an accuracy of one tenth percent across a range of fifty Celsius degrees. The beta-2 ASIC fabricated following the beta-1 has an infrared receiver on-board for programming the chip's functions. Using a high-power input, this chip has been demonstrated to transmit through three metal floors of a U.S. Naval vessel. An actual photograph of a chip fabricated using the data file that generates the artwork closely resembles this figure.

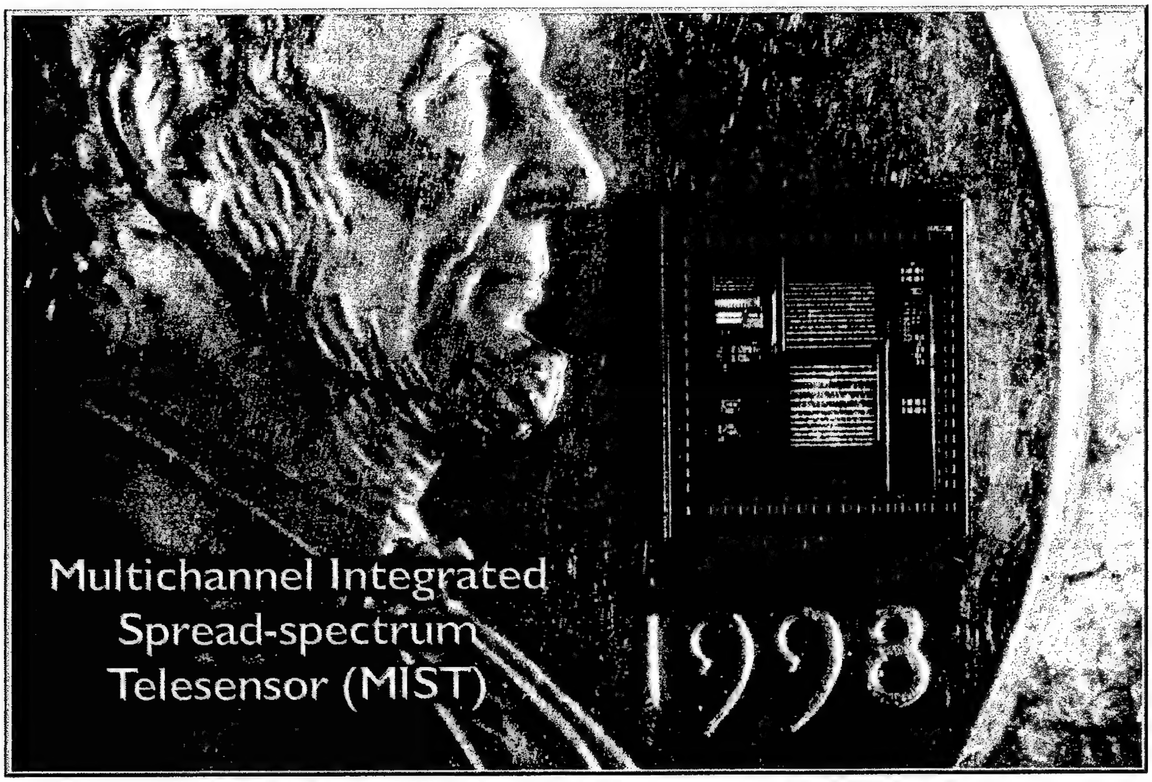


Figure 4.6. Beta-2 Version of the Temperature Telesensor ASIC. The design for this chip included an infrared receiver that can be used to control several on-board functions, including the duty cycle. The increased battery lifetime expected for thin-film polymer batteries in early 2000 will permit a heavier duty cycle without recharging such as may be needed when surgery is performed on a patient. A commercial button cell is used for testing this chip now and provides several million transmissions.

Figure 4.7. Simulated use of temperature telesensor (placed in ear canal of child) for home healthcare applications using a simple display/alarm executive unit. In this case the chip recognizes a sufficient temperature rise to warrant transmission to the bedside receiver in the executive unit. The unit then sounds an audible alarm and displays the temperature so that a parent can take appropriate action. A basic memory unit could record the event details. In such cases a fever can be detected early on and this is especially important in preventing febrile seizures. A more sophisticated executive unit could be in the form of a PCMCIA card for a handheld or laptop computer that could be connected to a remote computer, the pager network, or could include a telephone to dial 911 or any other appropriate telephone number.

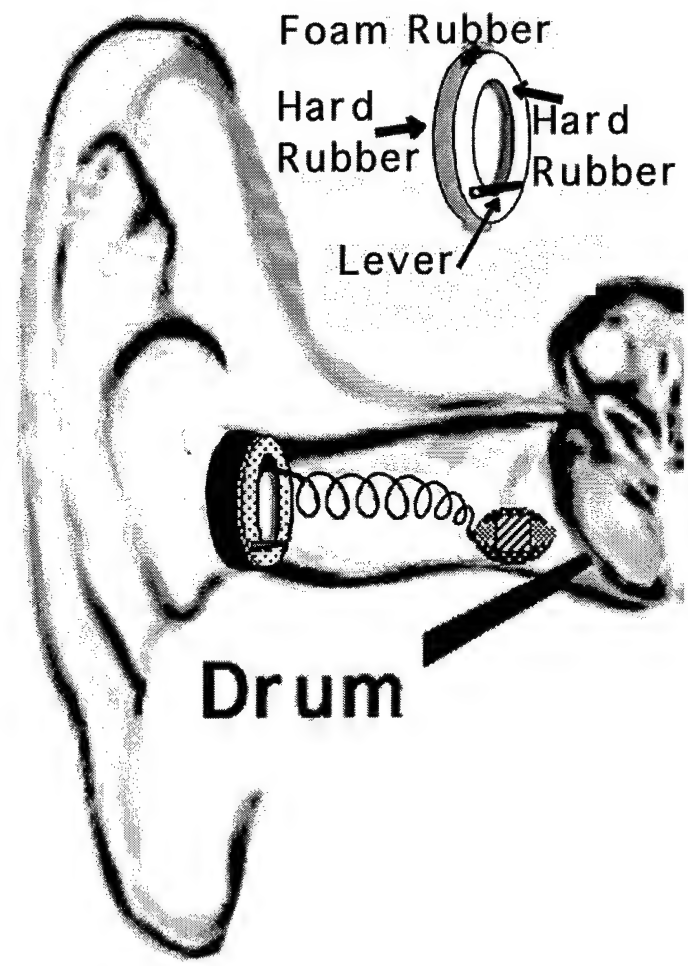


Figure 4.8. Preliminary Demonstration Mounting System for Temperature Telesensor. A hollow ear plug contains the ferrite-core toroidal antenna and battery as well as a crystal in one form. The device is placed firmly in the ear and held by a foam-rubber cushion. Sliding a small lever releases a weak spring that also serves as a connecting wire bundle. The spring pushes the coated telesensor well into the ear canal, but is too weak to damage the tympanic membrane. Once the system is in place the wearer soon becomes oblivious to its presence and there is very little loss of hearing. However, this is merely a preliminary mount for the demonstration system and an alternative system would be self-contained for mounting by a physician.

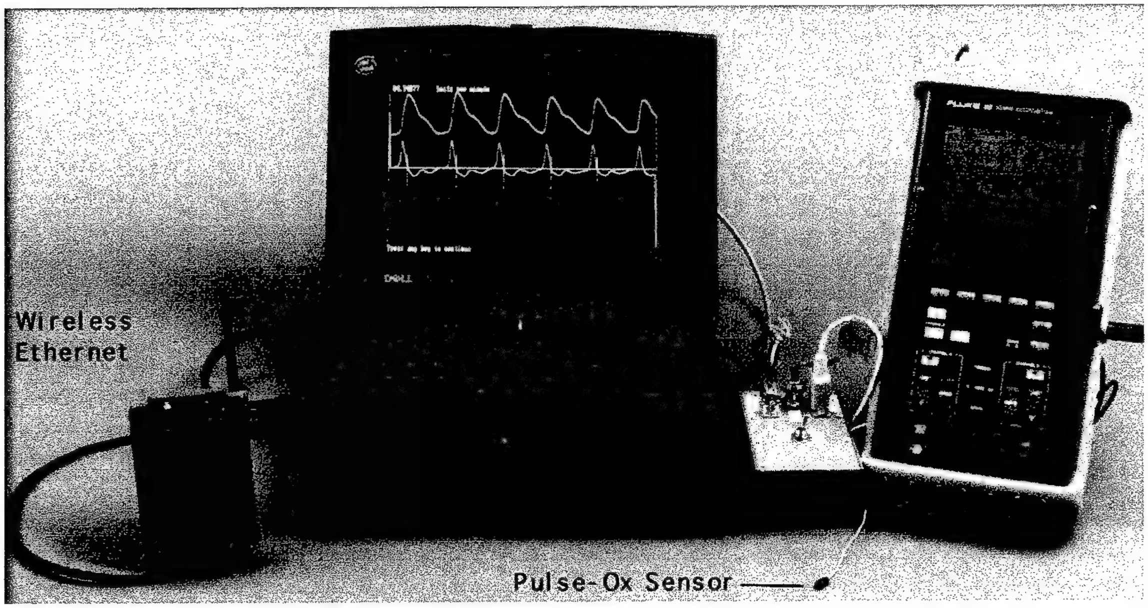


Figure 4.9. Benchtop pulse-oximeter test station. The sensor optically detects the signal and in this setup the pulse signal is first processed and displayed on an oscilloscope. It is then converted to digital form and our software displays the pulse waveform on a laptop computer. The zero crossings in the lower display (derivative) are used to count the pulses. As an example interface, this system was connected to the local area network via wireless ethernet. In current form, the sensor is itself wireless except for a degree of front-end processing, but both source control and the detector, signal processing, and transmission tasks are currently carried out with discrete components. By replacing these with an ASIC that contains our spread-spectrum radio transmitter, a pulse-oximeter telesensor can be fabricated that could be mounted on a finger ring or other small device.

Figure 4.10. Wireless Pulse-Oximeter Finger Ring. Three light-emitting diodes are shown in the bottom portions as the circular reddish portions. One of the light-emitting diodes provides a reference for the distance to the photodiode detector. The two signal-producing sources are sequentially lit by the electronics shown as the gray rectangular region. A duty-cycle receiver/controller appears as a dark oval connected to the other electronics by the yellow segment. The "stone" in the ring is a lithium-ion battery and the ring itself is an antenna and contains a wire bundle. Under the battery at the top of the ring is a photodiode detector, pre-amplifier, and the beta-model telesensor ASIC, including the crystal. The ring has a flexible fit and leaf springs to reduce motion artifacts which are further reduced by digital adaptive filters referenced to the auxiliary source. Comparison of the light absorbed at 670 nm and 780 nm produces the oxygen saturation level. The 780 nm source is used to track the pulse and its transmission is insensitive to skin color.

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6. Thomas L. Ferrell, Charles L. Britton, William L. Bryan, Lloyd G. Clonts, Michael S. Emery, M. Nance Ericson, Fabrice Meriaudeau, G. Wayne Morrison, Ali Passian, Stephen F. Smith, Tim D. Threatt, Gary W. Turner, and Alan L.Wintenberg, "Telesensor Integrated Circuits", *Proceedings of the National Institutes of Health Conference on Microdevices in Medicine* (San Jose, CA) (19-21 April, 1999). (Invited, Published by the Cambridge Healthcare Institute, Newton Upper Falls, MA)
7. T. L. Ferrell, P.B. Crilly, D.L. Hedden, and M.N. Ericson, "Pulse Oximetry Telesensor Ring", *Medicine Meets Virtual Reality VI Conference* (San Diego, CA), Jan. 22-26, 1998 (Invited)

APPENDIX A

RESUMES OF PRIMARY RESEARCHERS

Thomas Lee Ferrell

PRESENT POSITION: Group Leader, Photometrics and Senior Research Staff Member
Oak Ridge National Laboratory
Life Sciences Division
Bldg. 4500S, MS-6123
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Oak Ridge, TN 37831-6123
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EDUCATION: B.S. - Physics, Auburn University, Auburn, Alabama (1964)
Ph.D. - Physics, Clemson University, Clemson, South Carolina (1969)

EMPLOYMENT:

1969-1973 Assist. Prof., Physics Dept., Maryville College, Maryville, Tennessee.
1973-1974 Assist. Prof., Physics Dept., Hiram College, Hiram, Ohio.
1974-1978 Assoc. Prof., Physics Dept., Appalachian St. Univ., Boone, North Carolina.
1978-Present: Group Leader, Photometrics, Biochemical Physics Section, Life Sciences Division, Oak Ridge National Laboratory
and
Ford Foundation Professor, Dept. of Physics, Univ. of Tennessee, Knoxville

OTHER CURRENT ASSIGNMENTS:

Adjunct Professor:
Dept. of Physics, Clemson University
Dept. of Physics, Appalachian State University
Faculté des Sciences, Groupe Submicronique, Université de Bourgogne, Dijon, France
President, Fermac, Inc. Knoxville, Tennessee

HONORS:

Martin-Marietta Significant Event Award (1986, 1989, 1991), Martin-Marietta Inventor's Award (1986, 1989), Health & Safety Research Division Excellence in Research Award (1989), Research and Development Magazine R&D100 Award (1989), Fabry/Gramont Award of the Société Française Optique (1989), Inventor's Hall of Fame Advanced Technology Award (1992), Brussels World's Fair of Invention New Technology Award (1992), ORNL Approved Submission of Temperature Telesensor for Research and Development Magazine R&D100 Award (1999)

Thomas Lee Ferrell

CITATION INDEX:
OPEN SCIENTIFIC LITERATURE PUBLICATION

Average annual citations: 106/year (1989-1998)

PROFESSIONAL SOCIETY MEMBERSHIPS:

American Physical Society (APS)
American Association for the Advancement of Science
Sigma Xi Research Society
Sigma Pi Sigma Physics Honor Society

RECENT PUBLICATIONS/PRESENTATIONS/RESEARCH

RECENT PUBLICATIONS (Over 100 previous publications in the reviewed scientific literature)

F. Meriaudeau, E. Carver, J. Parks, Jr., K. Jacobson, R. Warmack, and T. Ferrell "Photon Scanning-Tunneling Microscopy of Unstained Mammalian Cells and Chromosomes", *Appl. Opt.*, **37** (31), 7276-7288 (1998)

F. Meriaudeau, T. Downey, A. Wig, A.Passian, M. Buncick, and T. L. Ferrell "Fiber Optic Sensor Based on Gold Island Plasmon Resonance" *Sensors and Actuators B*, **54** (1-2), 106-117 (1999)

F. Meriaudeau, T.R. Downey, A. Passian, A. Wig, and T.L. Ferrell, "Environmental Effects on Surface Plasmon Spectra in Gold Island Films: Potential for Sensing Applications", *Appl. Opt.*, **37** (34), 8030-8037 (1998).

T.R. Downey, F. Meriaudeau, A. Passian, A. Wig, T.L. Ferrell, "Guided Propagation in a Step Index, Multi-mode Fiber: Effect of Index Difference Variation on Allowable TM Propagation Constants", submitted to *Optics and Laser Technology*.

Thomas L. Ferrell, Fabrice Meriaudeau, Ali Passian, Jean-Pierre Goudonnet, and Andrew Wig, "Submicron Photolithography with the Photon Scanning-Tunneling Microscope" *Microscopy Today* (In Press for publication in June, 1999)

RECENT PRESENTATIONS

Thomas L. Ferrell, Charles L. Britton, William L. Bryan, Lloyd G. Clonts, Michael S. Emery, M. Nance Ericson, Fabrice Meriaudeau, G. Wayne Morrison, Ali Passian, Stephen F. Smith, Tim D. Threatt, Gary W. Turner, and Alan L.Wintenberg, "Telesensor Integrated Circuits", *Proceedings of the National Institutes of Health Conference on Microdevices for BioMedical Applications*, (San Jose CA) 19-21 April, 1999). (Invited)

Thomas Lee Ferrell

T.L. Ferrell, P.B. Crilly, S.F. Smith, A.L. Wintenberg, C.L. Britton, G.W. Morrison, M.N. Ericson, D.L. Hedden, D. Bouldin, A. Passian, T. Downey, A. Wig, and F. Meriaudeau, "Medical Telesensors", *Proceedings of the S.P.I.E Photonics West Conference*, (San Jose, CA) 198-203, 1998 (Invited)

T. L. Ferrell, P.B. Crilly, S.F. Smith, A.L. Wintenberg, C.L. Britton, G.W. Morrison, M.N. Ericson, D.L. Hedden, D. Bouldin, A. Passian, T. Downey, A. Wig, and F. Meriaudeau, "A Temperature Telesensor ASIC", *Proceedings of the Medicine Meets Virtual Reality VI Conference,* (San Diego, CA) Jan. 22-26, 1998 (Invited)

T. L. Ferrell, P.B. Crilly, D.L. Hedden, and M.N. Ericson, "Pulse Oximetry Telesensor Ring". *Proceedings of the Medicine Meets Virtual Reality VI Conference,* (San Diego, CA) Jan. 22-26, 1998 (Invited)

T.L. Ferrell, "The Future of Medical Telesensor Application-Specific Integrated Circuits", *Proceedings of the DARPA NextMed2 Conference,* (Boston, MA) April 9-11, 1999. (Invited)

Principal Investigator: Recent Projects Through June, 1999

Miniaturized Biosensor/Transmitter Systems, Defense Advanced Research Projects Agency, FY 1996-99

Amplitude Modulated Temperature Telesensor, University of Alabama, Birmingham Research Foundation, FY 1997-98

Optically Coupled Biosensors, Department of Energy, FY 1995-98

Nanometer-Scale Imaging, Department of Energy, FY 1995-98

CURRICULUM VITAE

PATRICK O'BRIEN, MD, FACEP

Address: 310 Timberhill Court
Farragut, TN 37922-1719

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(423) 544-8090 (work)
(423) 701-0442(pager)

Current Positions:
University of Tennessee Medical Center-Knoxville:

Assistant Medical Director
Emergency Department

Telemedicine Representative, Emergency Medicine
Telemedicine Center

Chief, Graduate Medical Education
Emergency Medicine

Chief, Continuous Quality Improvement
Emergency Medicine

Consultant, Emergency Medical Services and Telemedicine
Medical Officer for Corporate Development
Team Health, Inc.
Knoxville, TN

EMS Medical Director
Knoxville Fire Department
Division of EMS

Immediate Past President
Tennessee College of Emergency Physicians

Current Duties:
Provide direct patient care in Level I Emergency Department with census of greater than 48,000. Provide administrative, educational, and quality improvement direction in the Emergency Department. Provide Emergency Medicine expertise and direct research relating to EMS in the Telemedicine Center. Provide expertise in the fields of Emergency Medical Services and Telemedicine for the corporate management of Team Health, Inc. Provide medical advice to the Fire Chief and Deputy Fire Chief concerning quality improvement, protocols for medical care, and advice/assistance for emergency medical care in Knoxville. Direct the professional organization that represents over 270 full-time emergency physicians in Tennessee.

Prior Positions:
Staff Emergency Physician
Fort Sanders Regional Medical Center and Baptist Hospital of East Tennessee, Knoxville, TN

June 1988 - June 1995
Partner, Knoxville Emergency Physicians Group, PC

July 1989 - April 1995
Provided direct patient care for a combined census of 64,000 patients annually in two community emergency departments. Participated in the practice management of a 12-member private Emergency Medicine group practice.

Medical Director
Ambulatory Care of Tennessee, PC, Walk In Medical Center, Oak Ridge, TN

May 1990 - January 1991
Supervised the development, construction, and operation of a private practice-model ambulatory care center providing care to a service area of 68,000 people. Directed the marketing program of the practice in Knoxville and Oak Ridge. Provided direct patient care and occupational services to industrial and governmental clients.

Squadron Medical Officer, 110th Tactical Control Squadron, Tennessee Air National Guard (ANG)

July 1988 - November 1991, Directed the medical care and preparedness for an ANG combat squadron.

Chief, Prehospital Care
Department of Emergency Medicine, Wilford Hall USAF Medical Center, Lackland AFB, TX

July 1985 - June 1988
Supervised the activities of the Emergency Ambulance Service of the medical center which was comprised of 34 technicians. Provided direct patient care in a Level I Emergency Department of a 1000 bed medical center. Supervised medical students, interns, residents, medical technicians, and nurses in an emergency and prehospital care setting. Taught subjects relating to Emergency Medicine at the medical center including combat medicine. Represented the medical center in EMS affairs in the community. Participated in quality assurance and risk management audits on a daily basis. Coordinated the medical center's interaction with the military aeromedical helicopter service in San Antonio.

Education:

Vanderbilt University
Nashville, TN
BA cum laude (Biology, 1978)

Medical University of South Carolina
Charleston, SC
MD (1982)

Bowman Gray School of Medicine, Wake Forest University
North Carolina Baptist Hospital
Winston-Salem, NC
Emergency Medicine residency (1982 - 1985)
Chief Resident

1984 - 1985 Licensure: North Carolina, Tennessee, Virginia, Kentucky, Alabama

National Board of Medical Examiners

Board Certification: American Board of Emergency Medicine

Fellow, American College of Emergency Medicine

Physicians Additional Training: Advanced Cardiac Life Support

Provider, Instructor-Trainer Advanced Trauma Life Support and Basic Trauma Life Support

Instructor, Base Station Physician, Hyperbaric Medicine

Professional Memberships:

American Medical Association
1979 - 1991

American College of Emergency Physicians
1982 - Present

Emergency Medicine Residents Association
1982 - 1985

North Carolina Medical Society
1982 - 1985

Forsyth-Stokes-Davies Counties Medical Society, 1982 - 1985

North Carolina ACEP, 1982 - 1985

Government Services ACEP, 1985 - 1988

Member, San Antonio EMS Coordinating Committee, 1985 - 1988

Coordinator, Emergency Medicine, Continuing Medical Readiness Training, Wilford Hall USAF Medical Center, 1986 - 1988

Firefighter, Bexar County Volunteer Fire Corps, Company #4, 1986 - 1988

Vice President, Alamo Area Emergency Physicians, 1987

Member, Texas Association of EMS Physicians, 1987

Tennessee Medical Association, 1988 - Present

Knoxville Academy of Medicine, 1988 - Present

Member, Knox County EMS Committee, 1988 - Present

Tennessee ACEP, 1988 - Present

ACEP Section, Disaster Medicine, 1989 - 1991

American College of Occupational Medicine, 1989 - 1992

Treasurer, Tennessee ACEP, 1990 - 1991

President-Elect, Tennessee ACEP, 1992 - 1994

President, Tennessee ACEP, 1994 - 1996

Chairman, Provider Committee, Interfaith Health Clinic, 1990 - 1994

Member, Board of Directors, Interfaith Health Clinic, 1992 - 1994

Member, Board of Directors, Remote Area Medical, 1992 - Present

Chairman, Parish Needs Committee, St. John Neumann Catholic Church, 1991 - 1993

American Telemedicine Association, 1996 - Present

Member, Clinical Issues Committee, Division of EMS, Tennessee Department of Health

RESUME

Paul Benjamin Crilly
University of Tennessee
Electrical Engineering
314 Ferris Hall
Knoxville, TN 37996-2100
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Telephone: 423-974-5470, 423-974-5492(fax)

Research and teaching interests:

Telecommunications, digital signal processing, telesensors, biomedical signal processing, biomedical instrumentation, computer engineering.

Professional Positions

1989-present: University of Tennessee: Associate Professor of Electrical Engineering (tenured). Teach graduate and undergraduate courses, perform research in telecommunications, biomedical and computer engineering areas, supervise graduate students.

1994-95: U.S. House of Representatives, Legislative Aide for Congressman Rohrabacher. AAAS/IEEE Congressional Fellow. Advise member on science, environment and technology issues. Drafted policy papers, floor speeches, newspaper articles; gave talks to constituents, professional groups and government agencies. Have focused on the GATT and intellectual property legislation.

1990-95: University of Tennessee Medical Center: Adjunct Assistant Professor of OB-GYN.

1992-93: U.S. Army/Redstone Arsenal: Summer faculty fellowship. Do research in areas of image processing and neural networks.

1989-present: Oak Ridge National Laboratory: Consultant in area of signal processing, telemedicine.

1978-1989: Hewlett-Packard Company: Development engineer for computer workstation, chemical and biomedical instrumentation products. Worked in R&D, manufacturing and marketing.

.Professional Experience

Organizations: Chair/Vice Chair of East TN IEEE Section (elected); Director/Secy of TN Inventors Association (elected); UT Graduate Council (elected); UT Faculty Senate (elected)

Editorial Activities: Editorial board of two IEEE International Journals; reviewer for 3 other journals.

Publications: 1 book; 17 international peer-reviewed journal articles; 34 conference papers; 6 newspaper articles (authored or drafted); 15 invited talks; testified before U.S. Congress.

Patents: Hold three patents.

Travel: Bulgaria, Canada, France, Germany, Great Britain, Ireland, Mexico, Switzerland, Thailand.

Language: Spanish.

Education:

Ph.D.	1987	Electrical Engineering, New Mexico State University
M.S.	1978	Electrical Engineering, Rensselaer Polytechnic Institute
B.S.	1977	Electrical Engineering, Rensselaer Polytechnic Institute

APPENDIX B

ADDITIONS ADDRESSING REPORT REVIEWS

This report was reviewed by two reviewers and the recommended additions and information are contained in this Appendix.

1. Summary of Comments and Responses

1. It was suggested that patent applications be filed governing any intellectual property generated by the temperature telesensors. Unfortunately, the results having been publicly disseminated for a period exceeding one year, the central claims cannot be patented, but future developments may generate new patents if additional funding can be obtained for this project.

2. It was recommended that additional details be presented concerning the specific requirements of the project and how general requirements are specifically applicable to the sensors.

The specific requirements underwent a series of modifications during the project due to technological developments and the best available technology was used as it became available. No detailed military specifications were available for this project and the requirements were quite general in nature due to the unprecedented technology involved. This permitted some latitude in evolution of the technology. The objective was to demonstrate that a complete radio/sensor combination could be produced on silicon in such a way that vital signs could be offloaded without encumbering the performance of the warfighter. Further it was required that a technology transfer effort be initiated in order that private industry might produce telesensors in this form. The technology transfer was not detailed in the report, but the following was accomplished: A request for proposals was issued in the *Commerce Business Daily* and five respondents submitted acceptable proposals to commercialize the temperature telesensor based upon information and intellectual property agreements to be provided by the Office of Technology Transfer of Oak Ridge National Laboratory (as the major partner in the project). The proposals are under active consideration as of 7 September, 1999.

3. It was suggested that the results obtained might not be commensurate with the costs incurred.

Unfortunately, the cost of a single application-specific integrated circuit done by a commercial design firm begins at the level of one million dollars and rises to several tens of millions of dollars in the case of frontier technology, particularly when mixed signals are involved. This project cost was well below the typical commercial costs due to the past experience of the proposers that has allowed accumulation of many applicable design libraries funded by federal funds, the generosity of Synopsis, Inc. as they donated a \$7.3 million software package to the University during the project period, and to the relatively low cost of student labor. Additionally, a private donation of \$180,000 was obtained from Investment Management Associates, Inc. of Decatur, Alabama. Thus, the military investment was substantially augmented in order to achieve the product

development stage described in the main portions of the report. Nevertheless, there were serious obstacles faced in the project of an unrelated nature. Two example obstacles were that the software provided by the manufacturer for portions of the receiver unit did not in fact perform as claimed so that detailed, low-level, time-consuming, programming was required and the supplier of low-power, high brightness, light-emitting diodes for the optical pulse measurements went out of business. Alternative suppliers were not available since they have exclusive contracts with one of the leading manufacturers of pulse oximeters and with other companies. Additionally, we had signed a proprietary information agreement with another leading manufacturer of pulse oximeters, but this company was purchased by another firm, and we thereupon lost a considerable degree of technical aid. These factors played a damaging role in the project and only in the last month following the end of the project have these obstacles been overcome. Obstacles previously removed

4. It was mentioned that certain goals may not have been met by the project and that certain results were not sufficiently discussed with regard to the pulse oximeter. This is in fact the case. The pulse oximeter, while successfully demonstrated in the form of a wireless benchtop model, could not be reduced to silicon. The expense involved proved to be beyond that anticipated. A leading design firm, ASIC International, Inc. has since contracted with a manufacturer of pulse oximeters to provide an ASIC for signal processing of oximetric signals, the contract involved being well in excess of $1 million. While the system developed can be reduced to an ASIC at considerably lower cost through the University, the difficulties involved are clearly significant and the aforementioned difficulties with commercial concerns put the task beyond the reach of the project. An opportunity for a simpler ASIC that would have proven useful was lost during the project due to a delay in Presidential approval of the Defense Appropriations Bill, this delay having resulted in loss of skilled personnel.

5. A comment was made concerning the lack of cost figures for the devices themselves.

It is very difficult to do cost forecasting with new technologies. The cost of silicon-based devices can vary greatly. For example the price of random-access memory chips for desktop computers varied by over a factor of two in the past 12 months, dropping to as low as $1 per MB and rising to well over $2 per MB and then falling again. The price of production also varies considerably. However, in general, for digital circuits, the performance doubles and the price drops by half every 18 months (Moore's law). While mixed signal ASICs have a 2-3 year time frame for such changes, it is evident that a central achievement of the project is the provision of the first silicon form for telesensors and very substantial price reductions will ensue for the automated monitoring of vital signs. As a rough estimate, if a 10-cm silicon wafer in production is priced at $10,000 for a relevant number of masks, and if each temperature telesensor occupies nine square mm, then the on-wafer cost is $11 per telesensor. Wafer sizes continue to increase and processes are becoming cheaper at 0.5 μ linewidth, so this price will drop. Adding on-wafer testing, packaging, and other costs, the present temperature telesensor would be well below the cost of less accurate (1-2 degrees C vs. 0.1 C for the telesensor) digital thermometers that require manual application and longer acclimatization periods.

6. A concern was expressed related to the power spectrum. electronic signature, and electronic interference measurements.

These measurements have been carried out in detail, but the results are more easily summarized. The temperature telesensor was demonstrated on board a U.S. Navy Cruiser. By using a much greater than normal power, the signal was acquired through three (metal) floors of the cruiser the only route to the receiver being via leakage around the door seals. It was further demonstrated in a crowd at Washington Dulles Airport amidst at least two nearby users of cellular telephones. Finally, the system was demonstrated in the cardiology testing unit of a major hospital without incident. Since a 63-segment, direct-sequence, spreading is used, the system is immune from any but the most intense interference such as encountered near a major radio transmitter tower or other unusual locales that could saturate the receiver. Transmission is under the noise threshold and is provided in a 2 μs burst during which 10 mw are obtained from a trickle-charged capacitor. Normal power dissipation is 2-4 μw. The temperature telesensor has been demonstrated with the upcoming generation of thin-film Li-ion batteries to transmit over one million times without battery replacement. This testing was conducted under conditions similar to those evinced in the ear canal with varying external temperatures in a physical model, the temperatures being varied over sixty degrees C. However, the test results will be obsolete within one year as newer batteries become available and testing of internal mounting hardware permits better insulation without unacceptable impairment of hearing. The Norwegian military has recently developed a mounting system for intelligent hearing aids for tank crews. The electronics is still being committed to silicon, but the same hardware could be used permitting enhanced hearing (for conversation) in even very noisy environments, monitoring of temperature, pulse, and blood oxygen saturation. Since these are emerging developments, it was felt that detailed reporting of the present system would be misleading as to the feasibility of military use since there are major improvements which could be made at very low cost..

7. It was suggested that more information be given on the project work stages and procedures.

Each project followed the following sequence of tasks:

a. Construct sensor and electronics using discrete components. Optimize, correct design flaws, fabricate printed circuit board, test performance.

b. Use desktop computer to carry out as many tasks as possible in lieu of electronics at both the transmitter end and the reciever end.

c. Reduce the software on the desktop computer to a field-programmable gate array when appropriate or to a logic circuit to be placed on an ASIC.

d. Design, layout, and simulate the analog portions of the electronics on a computer workstation for reduction to silicon.

e. In the case of the temperature telesensor, as this was the first effort at the semsor and radio transmission on silicon, a fabrication at large linewidth was made. Once this was done, the reduction in linewidth was planned.

f. Work with fabrication foundry to convert digital fabrication process details to permit the process to be used for analog electronics.

g. Provide initial files at the 0.5 μ linewidth for the temperature telesensor to the foundry for a test iteration.

h. Redesign and resubmit files based on the initial experience.

g. Design and build a discrete component receiver unit interfaced to a laptop computer.

h. Develop software for the laptop computer and for the logic elements in the receiver.

i. Test the telesensor and receiver in a variety of environments.

j. Using experience with the temperature telesensor, repeat the above process (finished through stage of task c) for pulse oximetry, blood pressure, electrocardiogram, electroencephalogram, and respiration.

k. Transfer the technology to the private sector.

In summary, this project has achieved the goal of demonstrating telesensing of vital signs with discrete systems amenable to reduction to silicon, achievement of telesensing demonstration using silicon-based ASICs, initiation of substantial commercial technology activity, and demonstration of wireless transmission of vital signs over short range in noisy environments. Due to the emergence of several new technologies, it can be expected that costs and efficacy will dramatically improve during fiscal year 2000, and the fundamental work has been accomplished to position private industry to take advantage of the developments.

Footnote: This project has been demonstrated to the Special Operations Command at MacDill AFB, to the members of the U.S. Congress in the Dirksen Building as part of an exhibit sponsored by Senator William Frist, and to the National Institutes of Health.